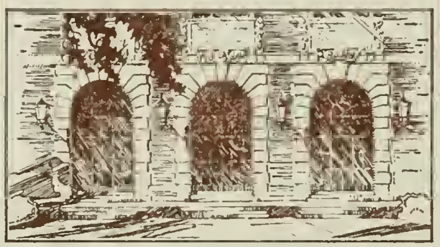

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CARDALERT: A PORTABLE, BATTERY-OPERATED, REAL-TIME ARRHYTHMIA DETECTOR AND ALARM SYSTEM

by

SIK KEE YUEN

July, 1976

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CARDALERT: A PORTABLE, BATTERY-OPERATED, REAL-TIME ARRHYTHMIA DETECTOR AND ALARM SYSTEM

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ABSTRACT

Cardalert is a portable, battery-operated real-time heart-beat processor and alarm system for high risk cardiac patients. Electrocardiograms taken from Lead II skin electrodes are converted into eight-bit digital data sequences. Digital differentiation is performed on the data and a feature-extraction approach is utilized to locate the Q, R, and S peaks. Comparison between the present RR-interval and a running average of the previous four normal RR-intervals is performed. Wide QRS durations are also noted. A conclusion is then derived from these parameters regarding the number and frequency of premature ventricular contraction (PVC) occurrences. An alarm is sent out when a presettable criterion is met to warn the patient of possible ventricular fibrillation. ECG tape analysis at 60 times real-time speed is possible by simply connecting the machine to an adaptor. Several arrhythmias are also recognized by the machine.

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1. INTRODUCTION

Since the mid 1960's when coronary care units (CCU's) were established as standard treatment areas for coronary patients suffering from acute myocardial infarction, the mortality rate for these patients has been significantly reduced from 30-40 percent down to 15-20 percent [1]. Unfortunately, heart attack is still the number one cause of death in the United States. As shown in Figure 1, cardiovascular disease contributed to more than half of the total deaths in 1972, of which more than 750,000 were coronary heart disease [2]. CCU's are undoubtedly a very effective means of monitoring and saving heart attack patients, but their general usage is hindered by the abruptness and danger of heart attacks. In 1964, Lewis Kuller and his co-workers at the Johns Hopkins School of Medicine analyzed all coronary deaths occurring in Baltimore in one year and found that only 34 percent of those stricken survived long enough to be hospitalized [3]. Bainton and Peterson of the U. S. Public Health Service did a similar study based on 122 coronary fatalities among people under 50 years of age and found 63 percent died within an hour. Only 23 percent of the heart attack victims lived long enough to be medically attended [3]. These reports suggest that about two-thirds of coronary fatalities actually occur outside the confines of hospitals.

It is now known that ventricular fibrillation is the most common form of these final heart attacks. When ventricular fibrillation occurs, the heart muscles enter into a completely unstable, chaotic state. Blood circulation becomes very ineffective. If treated within one minute, the chance of survival is about 90 percent. However, a delay of three minutes usually means less than 10 percent chance of survival because of extensive heart muscle injury and brain damage. Defibrillation by means of electrical impulses

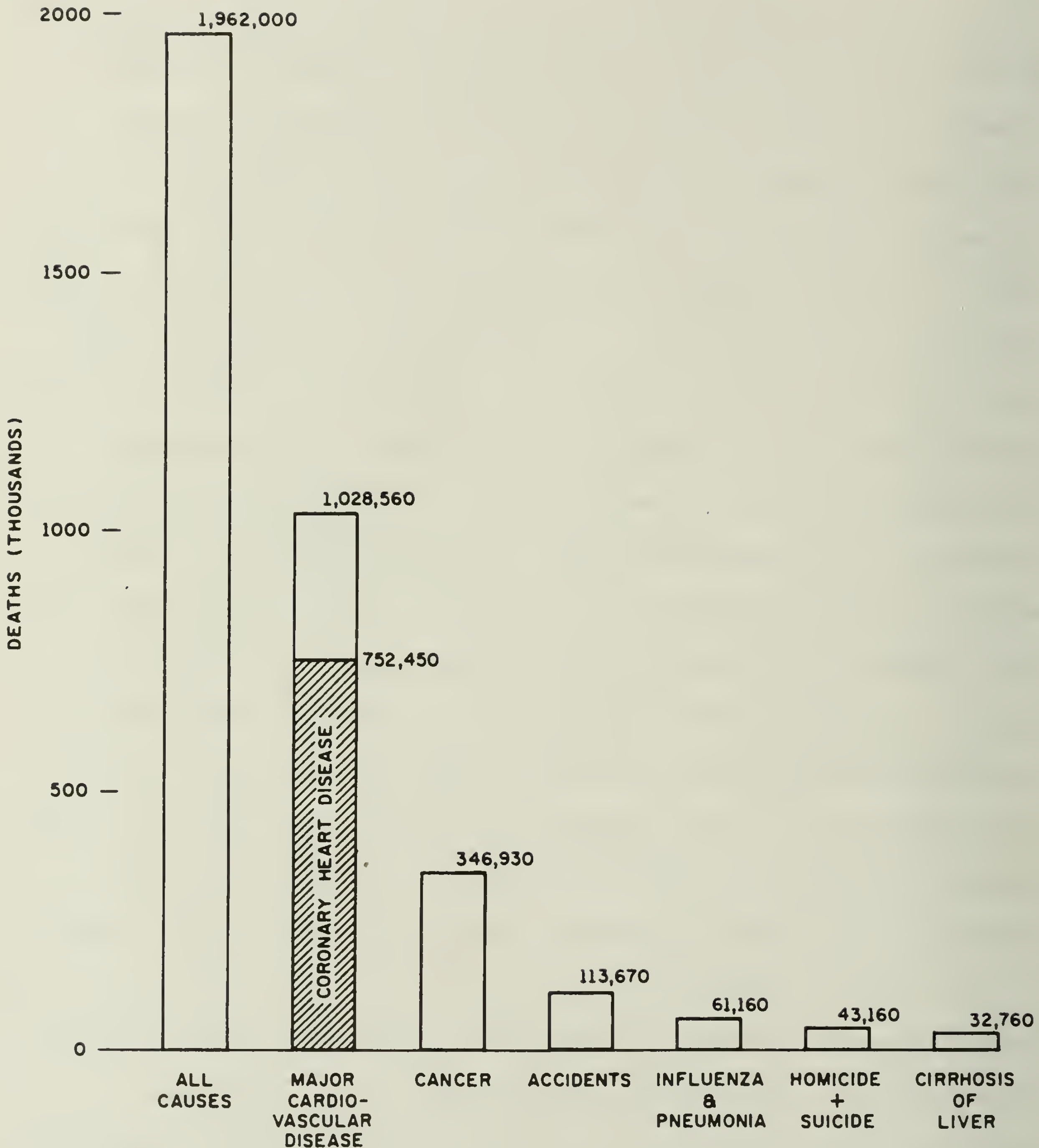

Figure 1. Histogram of Major Causes of Death in the U.S. in 1972.

generated from capacitive or AC sources can effectively reverse fibrillation but their applications are essentially limited to hospital facilities.

The establishments of CCU's also enabled observations that other arrhythmias usually precede ventricular fibrillation, among which premature ventricular contractions (PVC) are the most frequent. These arrhythmias may occur 72 hours before the onset of ventricular fibrillation and persists for several days or even months after attack. It is now confirmed that PVC's are directly responsible for the occurrence of ventricular fibrillations. If PVC's are suppressed by antiarrhythmic agents, ventricular fibrillation rarely occurs. Therefore, heart attacks, sudden as they appear, are not unannounced after all.

Recent advances in electronics and hence computers have prompted automatic monitoring of patients in CCU's. Special attention is paid to PVC's regarding their numbers and frequency of occurrence. However, these sophisticated machines cannot contribute much in terms of saving extra lives. Since most heart attacks occur outside the hospitals, these machines essentially serve to relieve the load of CCU personnel and facilitate quicker and more complete information storage and processing. On the other hand, if a portable machine is built which constantly monitors the heart beats of high risk cardiac patients, a lot of lives can be saved. Such a machine should detect PVC's and send out an alarm when some preset conditions are met. This thesis is concerned with such a device called Cardalert [4] (Cardiac Alert System) which is to be worn by high risk coronary patients without confining them to hospitals and hindering their daily activities. It is a small, portable, battery-operated arrhythmia detector and alarm system which warns the patient of dangerous PVC levels. Besides PVC, several other arrhythmias are also detected. In the next chapter

of this thesis, a very brief review of the heart anatomy and its electrical activity is presented. The following chapter proceeds to survey the different approaches for building an arrhythmia detector. The algorithm of Cardalert will be discussed in detail. Finally, the system evaluation, projections and system improvement are considered in the last chapter.

2. ANATOMY AND ELECTROPHYSIOLOGY OF THE HEART

The heart is esentially a pump which circulates blood throughout the body. An adult heart pumps about five ounces of blood at each stroke, or about 4000 gallons a day [5]. The heart is divided into four chambers (Figure 2), the right and left auricles (atria) which serve as reservoirs, and the right and left ventricles which serve as the main pumping units. Venous blood enters the heart into the right auricle and is pumped into the lungs by the right ventricle. The oxygenated blood re-enters the heart into the left auricle, and is pumped forcibly by the left ventricle to circulate throughout the body. The pumping actions of the heart are achieved by controlled contractions and relaxations of the various heart muscles which are in turn controlled by electrical impulses that spread throughout the muscle tissues and nerve systems of the heart.

In the resting state, the electrically active cells of the heart muscles maintain a steady electrical potential across their cell membranes. This "resting transmembrane potential" remains stable until the arrival of an electrical impulse which triggers rapid and complete discharge of the resting potential. After this, the cell recharges or repolarizes slowly to its original resting potential and remains steady until the next electrical impulse. There are also some special cells called pacemaker cells which possess an automicity characteristic. These cells, instead of maintaining a steady resting potential, discharge spontaneously but slowly until a threshold voltage is reached when they rapidly and completely depolarize. Repolarization follows the depolarization and the whole process begins again. When the cells depolarize, they contract. When they repolarize, they relax and remained relaxed throughout the resting state. Macroscopically, the muscles contract during depolarization and relax during repolarization.

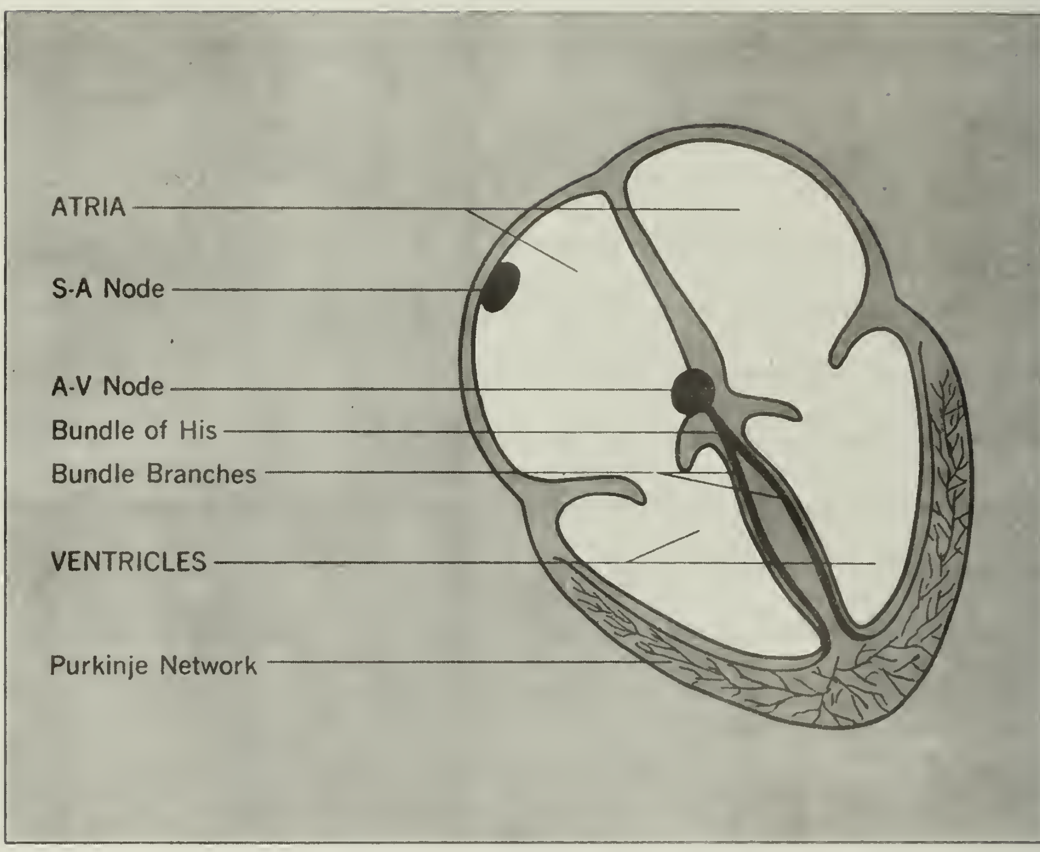

Figure 2. Diagram Showing Distribution of Specialized Heart Muscle [6].

The automatic pacemaker cells in the sinus node or sinus-atrial node (SA node) normally initiate the cardiac electrical impulse and have a physiologic periodicity of 60 to 100 impulses per minute. The ones at the atrial-ventricular node (AV node) have a periodicity of 40 to 60 per minute while those in the ventricles have a rate of 20 to 40 per minute. This built in arrangement of decreasing inherent rates at lower levels serves as a preventive or "fail-soft" mechanism so that the lower pacemaking centers can automatically assume the responsibility of pacemaking if the upper pacemakers fail, but under normal physiological conditions, will not usurp the pacemaking function. In addition, there are several cell types which normally do not display automicity. They would, however, become automatic as a result of pharmacologic or pathologic influences.

During the normal course of heart function, an electrical impulse is initiated at the SA node. This electrical activity spreads into the surrounding atrial tissue and is conducted through the atria to the AV node. This inpulse then passes the AV node into the common bundle of His and thence through the right and left bundle branches into the ventricles through the ramification of the Purkinje network. In the electrocardiogram (EKG or EGG), Figure 3, the P peak corresponds to the depolarization of the atria while the QRS complex refers to that of the ventricles. T wave is due to ventricular repolarization. More detailed nomenclature of the ECG waveform is given in Figure 4 and the various conduction speeds of the different conduction media of the heart is given in Table 1. Note that the velocity is most rapid in the Purkinje fibers which results in rapid and forceful contraction of the ventricles. It is slowest in the midportion of the AV node. The characteristics and average values of the various intervals are given in Table 2.

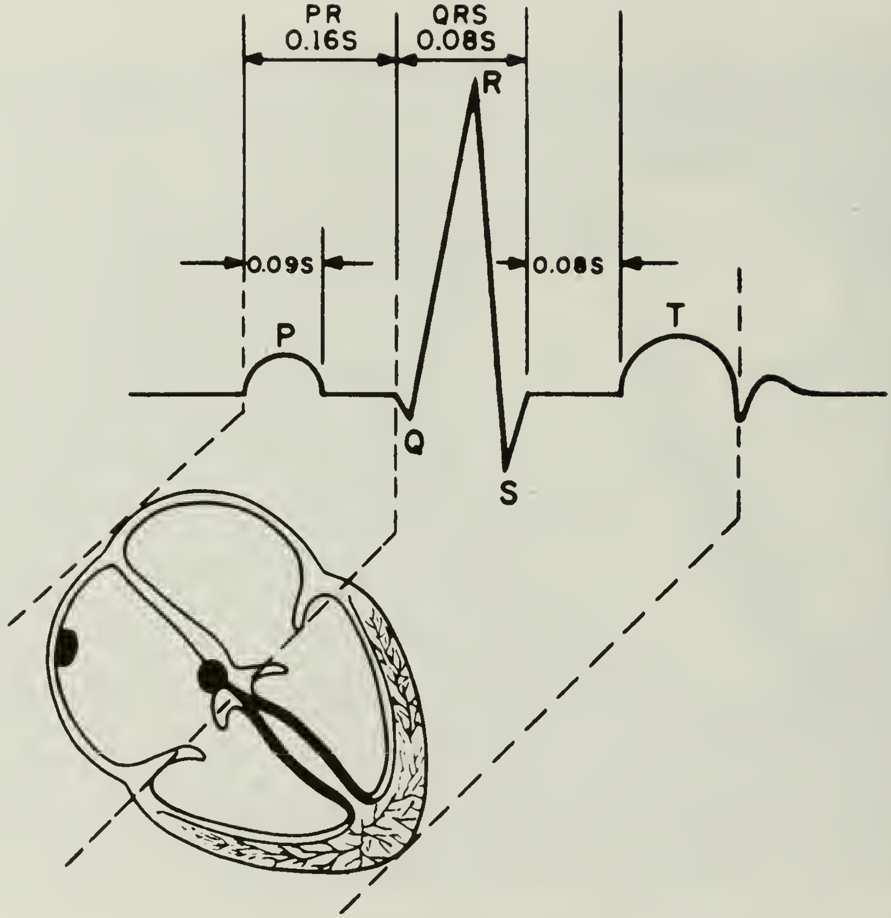

Figure 3. Relationship of ECG to the Heart (the time durations are average values)

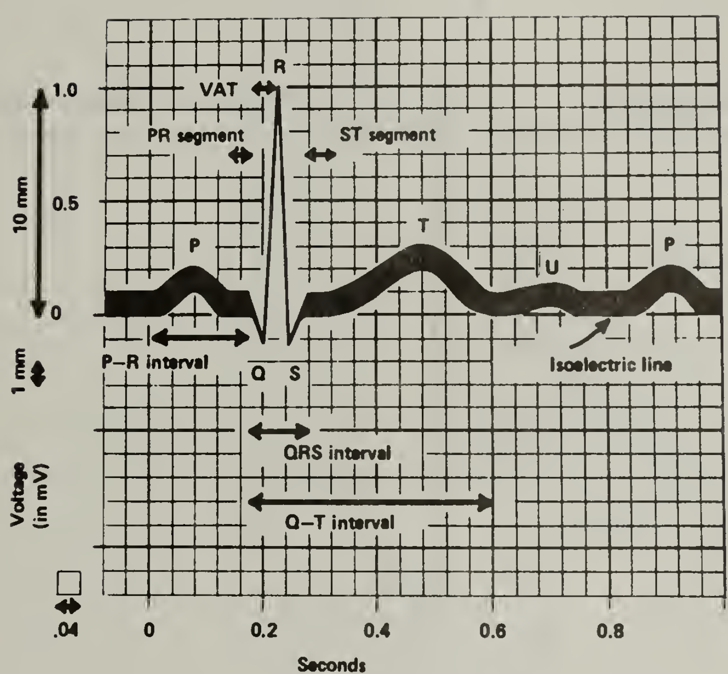

Figure 4. Diagram of Electrocardiographic Complexes, Intervals, and Segments [7].

Table 1. Conduction Velocity of Electrical Impulse in the Heart [7].

Conduction medium	Velocity (meter/second)
SA node	0.05
atrial muscle	0.8 - 1
AV node	0.05
bundle of His	0.8 - 1
Purkinje fiber	4
Ventricular muscle	0.9

Table 2. Main Characteristics of the Normal Electrocardiagram (based on Lead II electrodes) [8].

	P Wave	P-Q Segment	QRS Complex	T Wave	U Wave
Direction	Up	Usually depressed; may be elevated	Up	Up	Up or absent
Contour	Smooth and rounded; may be peaked or show tiny notches.	Horizontal, may slope down or have a downward convexity.	Tallest wave on the ECG. The negative slope is usually steeper than the positive.	Rounded	Rounded
Duration	0.06 - 0.11 sec.	0.12 - 0.21 sec.	0.06 - 0.10 sec.	0.05 - 0.25 sec,	Not significant

2.1 Arrhythmias

Arrhythmias are abnormal activities of the heart which inevitably cause distortions of the ECG waveform. Arrhythmias are the result of disorders in automicity of the pacemakers or faults in conduction or a combination of both. Due to drug or physiological changes, automicity may either be increased or decreased. Depending on the origin and the mechanism of disorder, arrhythmias can be broadly classified as in Table 3. A complete list of all the numerous arrhythmias and their ECG waveforms is difficult. Since Cardalert is concerened with arrhythmic phenomena which cause sudden death and those which precede fatal arrhythmias, only these arrhythmias will be discussed in some detail in the following. It should be noted that all of these arrhythmias are ventricular arrhythmias as expected, since it is the ventricles that are directly responsible for the blood circulation.

2.2 Ventricular Tachycardia and Ventricular Flutter

Ventricular tachycardia is a rapid heart action with a rate between 130 - 220 beats per minute. It is usually associated with coronary artery occlusion or as a manifestation of digitalis or quinidine intoxication and/or electrolyte disturbances. The arrhythmia is potentially very dangerous; unless successfully terminated, mortality is highly likely.

On the ECG, ventricular tachycardia is seen as a cluster of wide, bizzare QRS complexes interrupting the regular sinus rhythm. The QRS durations are greater than .1 second and the rhythm is slightly irregular, as shown in Figures 5 and 6.

Ventricular flutter is not a distinct entity, but rather as the extreme end of the spectrum of ventricular tachycardia, bridging it with ventricular fibrillation. It is characterized by very regular, smooth ventricular waveforms at a rate of 150 - 300 beats per minute. Cardiac output during this arrhythmia

Table 3. Classification of Arrhythmias [7]

Disturbances of Impulse Initiation

A. Rhythms initiated in the sinus node. [(Regular) sinus rhythm is the normal.]

1. Sinus tachycardia
2. Sinus bradycardia
3. Sinus arrhythmia
4. Wandering sinus pacemaker

B. Rhythms of ectopic origin

1. Passive ectopic rhythms (following depression of higher pacemakers or block of the impulse arising in them)
    a. A-V nodal rhythm*
    b. A-V nodal escape
    c. Idioventricular rhythm
    d. Ventricular escape
    e. Wandering pacemaker between the sinus and the A-V nodes
2. Active ectopic rhythms (following enhancement of the subordinate pacemaker)
    a. Premature systoles (of auricular, A-V nodal, or ventricular origin--rarely of sinus origin)
    b. Paroxysmal tachycardia (of auricular, A-V nodal, or ventricular origin)
    c. Chaotic heart action (of auricular, ventricular or mixed origin)
    d. Auricular flutter (chronic or paroxysmal)
    e. Auricular fibrillation (chronic or paroxysmal--fine or coarse, or impure auricular flutter)
    f. Ventricular flutter and fibrillation
    g. Reciprocal rhythm

Distrubances of Impulse Conduction

A. Interference (impulses reaching regions of the heart while they are still in the normal refractory state)

1. Isolated interference
2. Dissociation

B. Heart block (depression of the ability of part of the heart to transmit the impulse)

1. S-A (sino-auricular) block
2. Intra-auricular block
3. A-V (auriculo-ventricular) block)
4. Intraventricular block
5. Alternans of the heart

C. Anomalous A-V conduction path (shortened P-R-prolonged QRS combination)

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*Nodal tachycardia and, more rarely, nodal arrhythmia

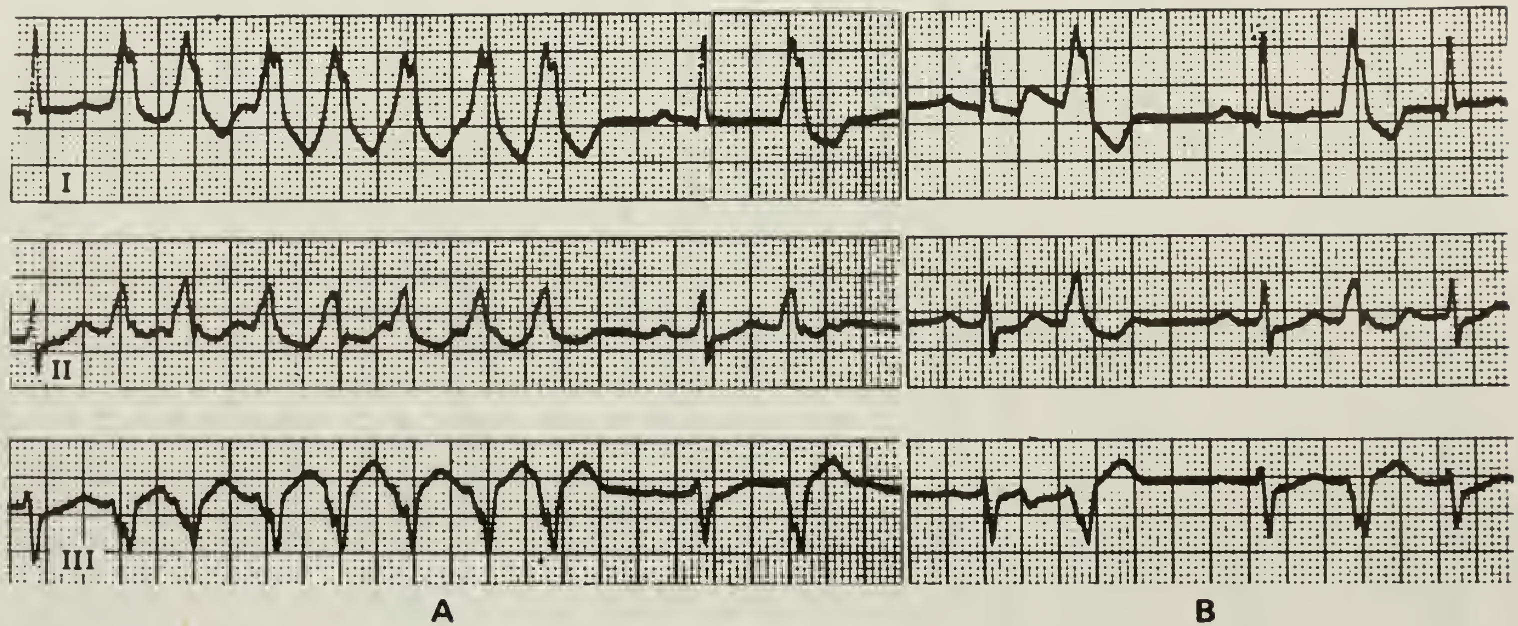

Figure 5. Ventricular Tachycardia (rate = 150) [7].

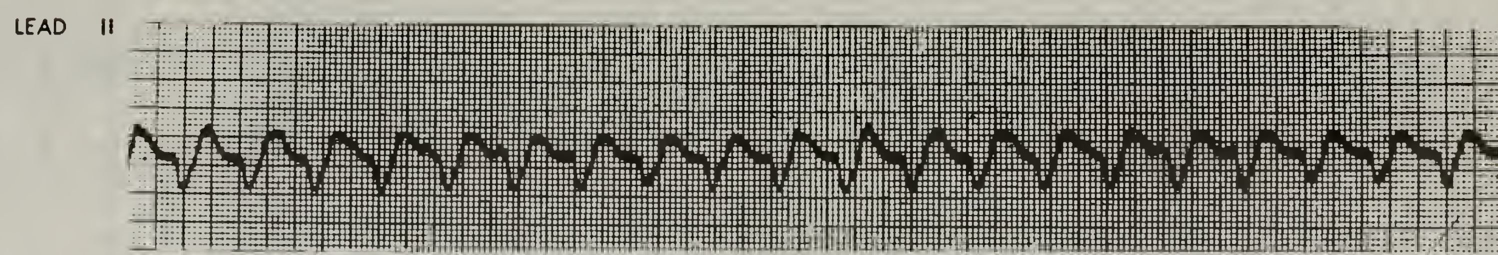

Figure 6. Another Example of Ventricular Tachycardia (rate = 136) [9].

is greatly reduced. It very rarely persists very long before developing into ventricular fibrillation. Figure 7 shows the ECG of the arrhythmia. Note that atrial rhythms are not noticable.

2.3 Ventricular Fibrillation

Ventricular fibrillation occurs as a totally random, unorganized depolarization of the ventricular musculature. Cardiac output during ventricular fibrillation is almost non-existent. It is believed to be the cause of most sudden deaths. The most common cause is myocardial infarction and it shares the same conditions that cause ventricular tachycardia. Diagnosis of this arrhythmia must be done with ECG since the peripheral pulses are not palpable and the heart beat is inaudible.

Ventricular fibrillation exists in two forms as shown in Figure 8. Depending on the setting in which the arrhythmia occurs, the coarse fibrillation is treatable with a defibrillator and skilled personnel. Fine fibrillation, however, frequently precedes the complete cessation of electrical activity at the time of biological death of the heart and is very difficult to defibrillate. Note also the completely random waveform in the ECG.

Ventricular fibrillation is easily differentiated from cardiac standstill. The ECG of the latter simply displays a straight line, possibly with a few P waves. No ventricular activity can be detected in this case. Ventricular standstill is usually associated with long-standing degenerative or ischemic heart disease.

2.4 Premature Ventricular Contraction (PVC)

PVC's are the result of one or more ectopic foci in the ventricular myocardium. It occurs in all age groups, normal people as well as those with organic heart disease. The patient may be completely asymptomatic or may experience only annoying symptoms such as palpitations. On the other hand, it

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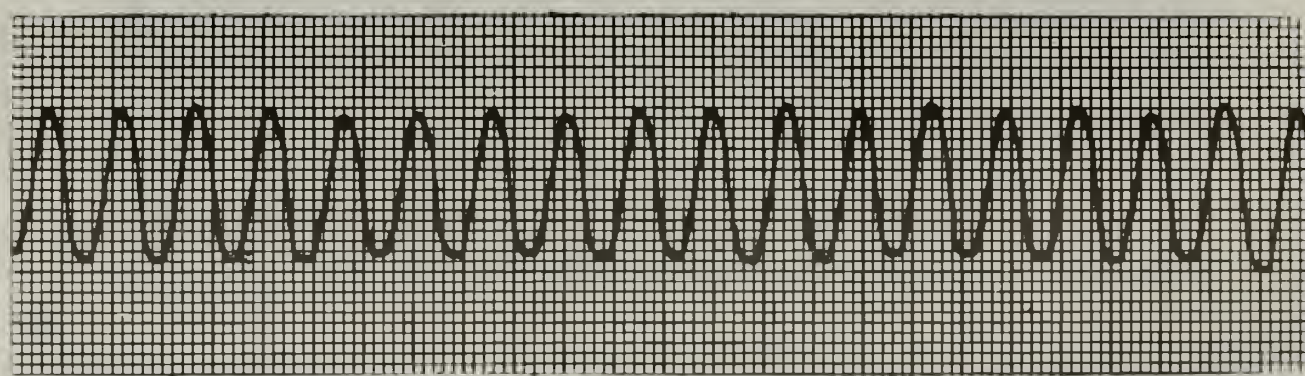


Figure 7. Ventricular Flutter (rate = 207) [9].

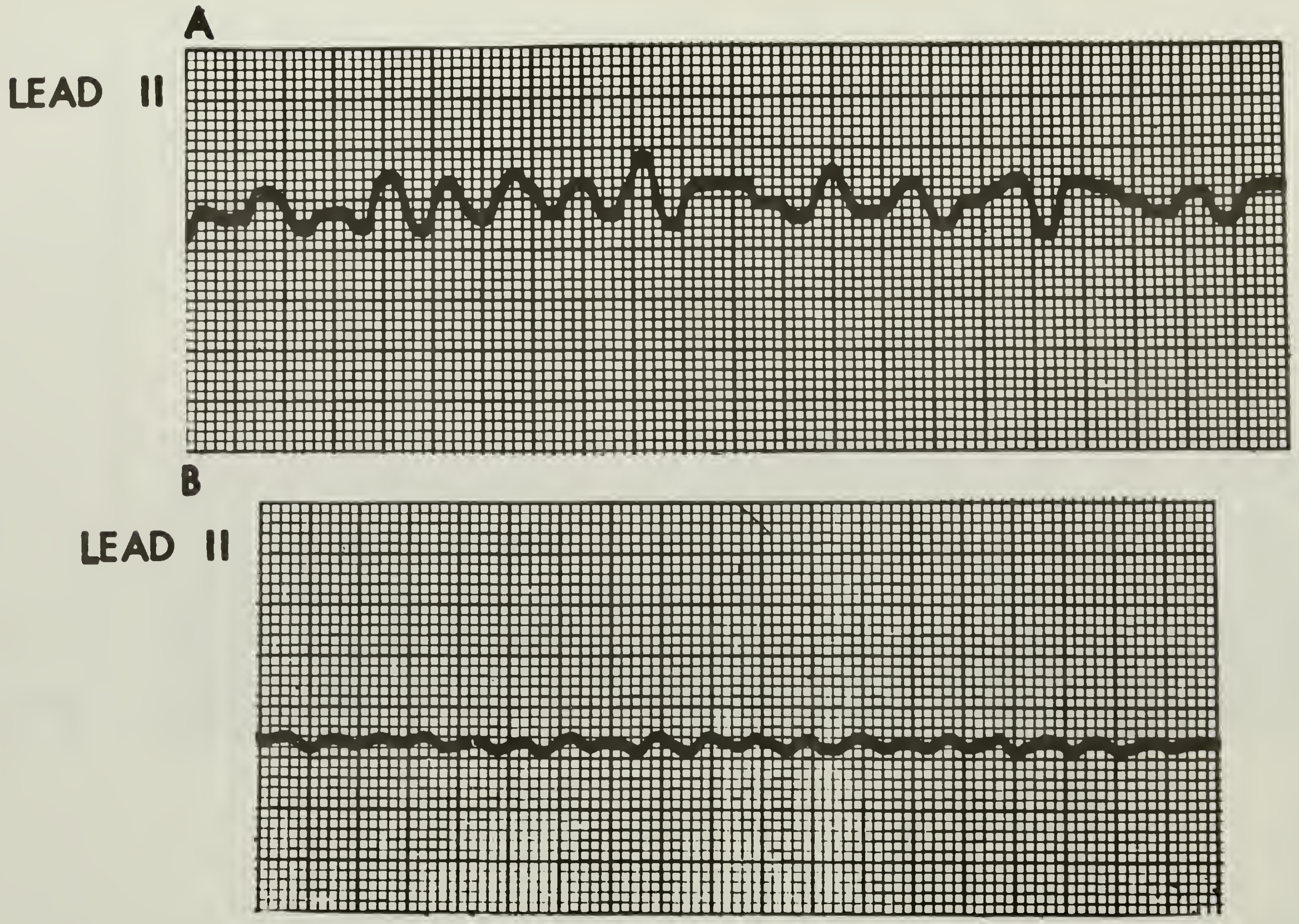


Figure 8. Coarse and Fine Ventricular Fibrillation in A and B Respectively [9].

may trigger ventricular tachycardia and/or ventricular fibrillation. It is therefore the nature of the underlying heart disease that determines the significance of the PVC's.

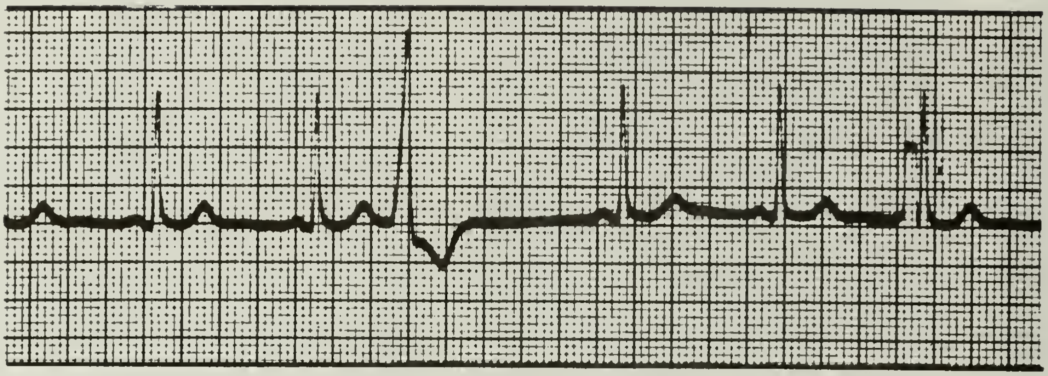
Its electrocardiogram, as shown in Figure 9; displays a premature ventricular activity with a wide, bizzare QRS greater than .1 second in duration. Since its occurrence places the ventricles in the refractory state (a condition during which the particular heart muscle concerned no longer reacts to any electrical impulse), the following atrial activity is obscured until the next one. This corresponds to the compensatory pause usually associated with PVC's. Thus two full sinus cycles enclose the PVC.

These several arrhythmias just mentioned constitutes those that are most dangerous and therefore, of most concern. Several other arrhythmias of no potential danger are readily detected by the structure of Cardalert. Their characteristics, along with the important ones, are listed in Table 4.

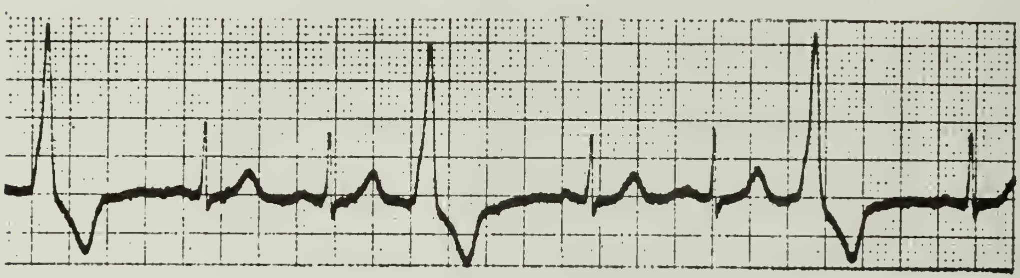
2.5 The Relationship Between PVC's and the Fatal Arrhythmias

The original idea of the CCU was to staff a group of skilled personnel for the caring of coronary heart patients. Experience gathered from continuous monitoring of these patients revealed that there is a profusion of irregular heart rhythms, especially PVC's, before and after a heart attack [3,10]. A high correlation relation between PVC's and the fatal arrhythmias such as ventricular tachycardia and ventricular fibrillation has been confirmed by experiments on animals and observations on coronary patients.

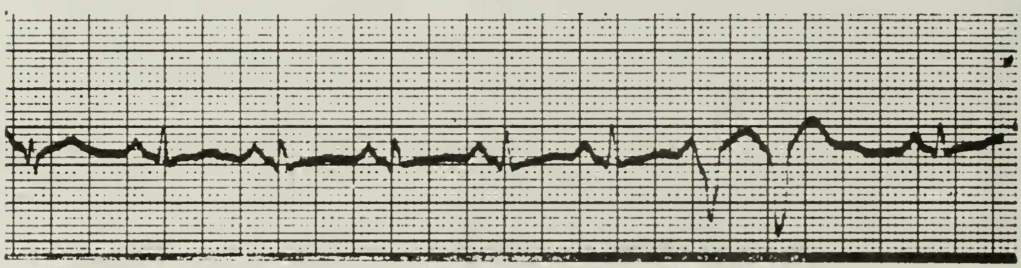
By artifically inducing coronary occulusions on experimental dogs, it was found that PVC's occurred in large numbers before they died and they all died of ventricular fibrillation if it happened within a few days. It was also found that when antiarrhythmic agents were used to suppress PVC's on another group of dogs, none of them died of ventricular fibrillation. It



Premature Ventricular Contraction



Frequent Premature Ventricular Contractions



Premature Ventricular Contractions Paired

Figure 9. Premature Ventricular Contractions [6].

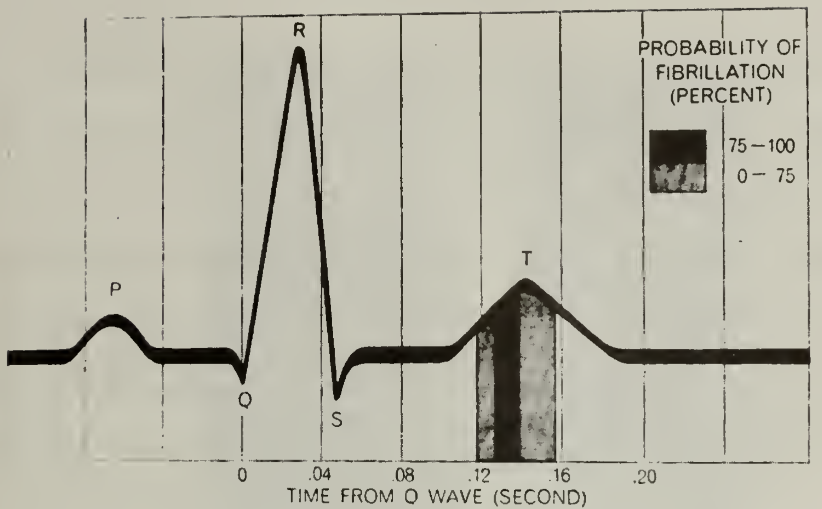
Table 4. Characteristics of the Arrhythmias Detected by Cardalert

Arrhythmia	Characteristics
Ventricular Asystole & Fibrillation	A period exceeding 2 seconds without QRS*
Ventricular Extrasystoles (PVC's)	R-R intervals occurring within 80% of the average interval duration and QRS duration > 0.1 s.
Ventricular Tachycardia	Ventricular rate > 120 bpm and QRS duration > 0.1 s
Bradycardia	< 50 bpm < 40 bpm
Aberrancy	QRS > 0.1 s

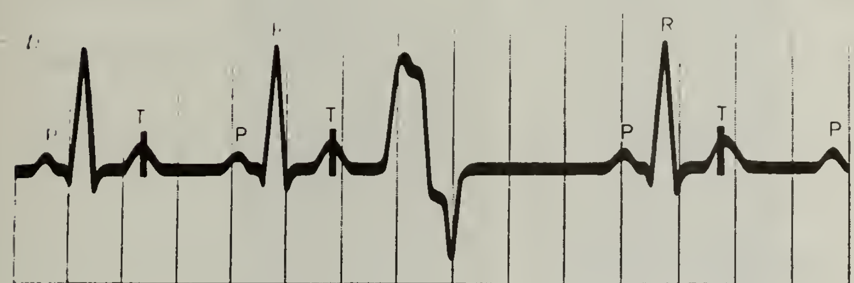
*In ventricular asystoles, undulations are entirely absent while in ventricular fibrillation, continuous, small, uneven undulations are typical.

was found later that a vulnerable period exists in the T-interval of the ECG after each ventricular depolarization. This period is about 0.02 to 0.04 seconds in duration. If an electrical impulse stimulates the heart muscle during this period, ventricular fibrillation can result. It is also found that a significantly larger electrical impulse is required to trigger ventricular fibrillation on normal hearts than on those with myocardial infarction. In fact, on those hearts with myocardial infarction, the threshold of ventricular fibrillation is so low that an otherwise harmless PVC can precipitate the fatal arrhythmia. This phenomenon is illustrated in Figure 10. A real case was recorded in Figure 11. By continuous monitoring of these experimental dogs, it was also found that ventricular fibrillations occur only when PVC's trigger them during the vulnerable period.

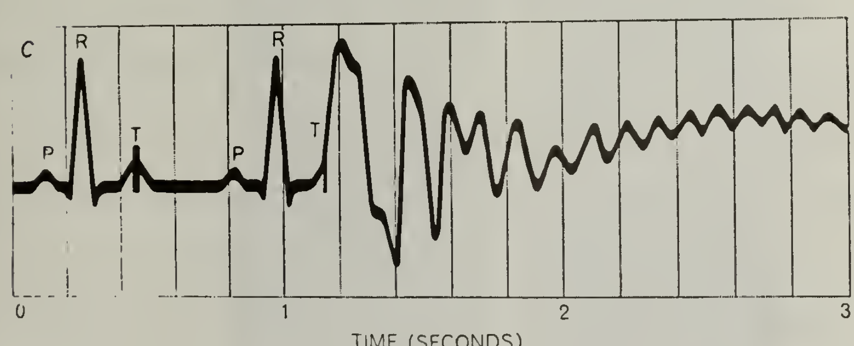
Since these findings, antiarrhythmic agents such as lidocaine, commonly used by dentists as local anesthetic, are used on patients until PVC's are reduced. As a result, deaths in the coronary case unit (CCU) from arrhythmias are significantly reduced. Lown reported in 1968 [3] that of the 520 patients observed during the first few years of operation of the CCU in the Peter Bent Hospital, only one percent developed ventricular fibrillation compared to 15 percent expected before the use of antiarrhythmic agents. It is obvious then that sudden deaths caused by ventricular fibrillations are not unannounced after all. IF PVC's can be effectively detected and proper drugs administered, sudden deaths can be greatly reduced.



(a) The vulnerable period



(b) Occurrence of harmless PVC



(c) A PVC occurred in the vulnerable period and triggered ventricular fibrillation

Figure 10. Vulnerable Period [3].

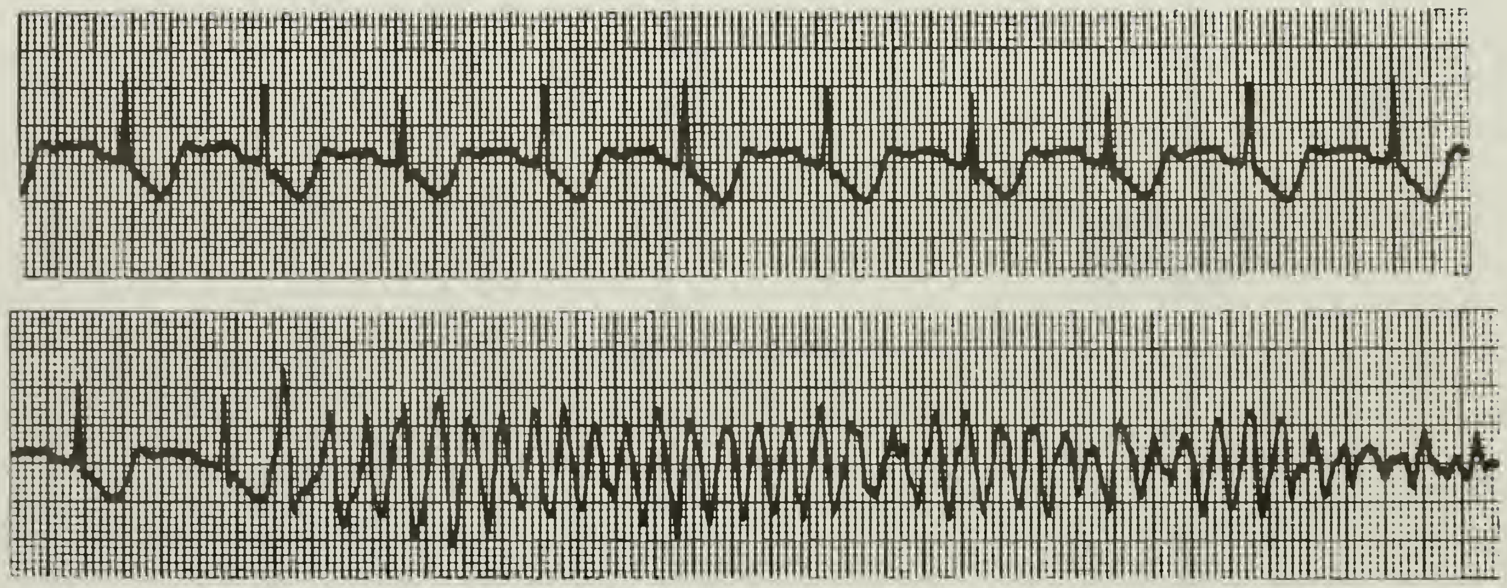


Figure 11. A PVC Occurred in the Vulnerable Period of a Regular Sinus Rhythm and Triggered Ventricular Fibrillation [7].

3. SYSTEMS OVERVIEW

The establishment of CCU's has promoted the use of computers in the automatic, continuous monitoring of coronary patients. Many systems have been developed in various laboratories, universities, and hospitals all over the world. Generally speaking, there are basically two approaches to the problem; one is based on the frequency characteristics or on a mathematical model while the other approach relies upon the timing, durations, and morphological features of the ECG. In almost all of these systems, the primary goal is to detect the occurrence of PVC's.

3.1 Frequency Spectrum of the ECG and Noise Consideration

The normal ECG is basically a low frequency waveform. Its main characteristics are found between 1 Hz to 40 hz as shown in Figure 12. More specifically, the maximum spectrum value occurs at the fundamental of 1.22 Hz, the -20 db point at 36 Hz, -40 db at 105 Hz, and -60 db at 300 Hz [11]. As shown in Figure 13, the P and the T waves occupy the very low portion of the spectrum. The QRS complex, on the other hand, occupies the high frequency end. A careful analysis of the QRS complex itself reveals that the downward R-S slope has the largest slope value with the longest duration. This important feature is employed in a few of the systems to be summarized later.

One problem associated with the real time analysis of ambulatory ECG is to differentiate it from the everpresent noise. Sixty Hertz noise is easily picked up by the patient. Higher frequency artifacts produced by muscle tremors are also commonly encountered. Low frequency baseline drifts are easily generated by electrode movement and/or the patient's movements. Figure 14 shows such a recording strip mingled with a lot of noise.

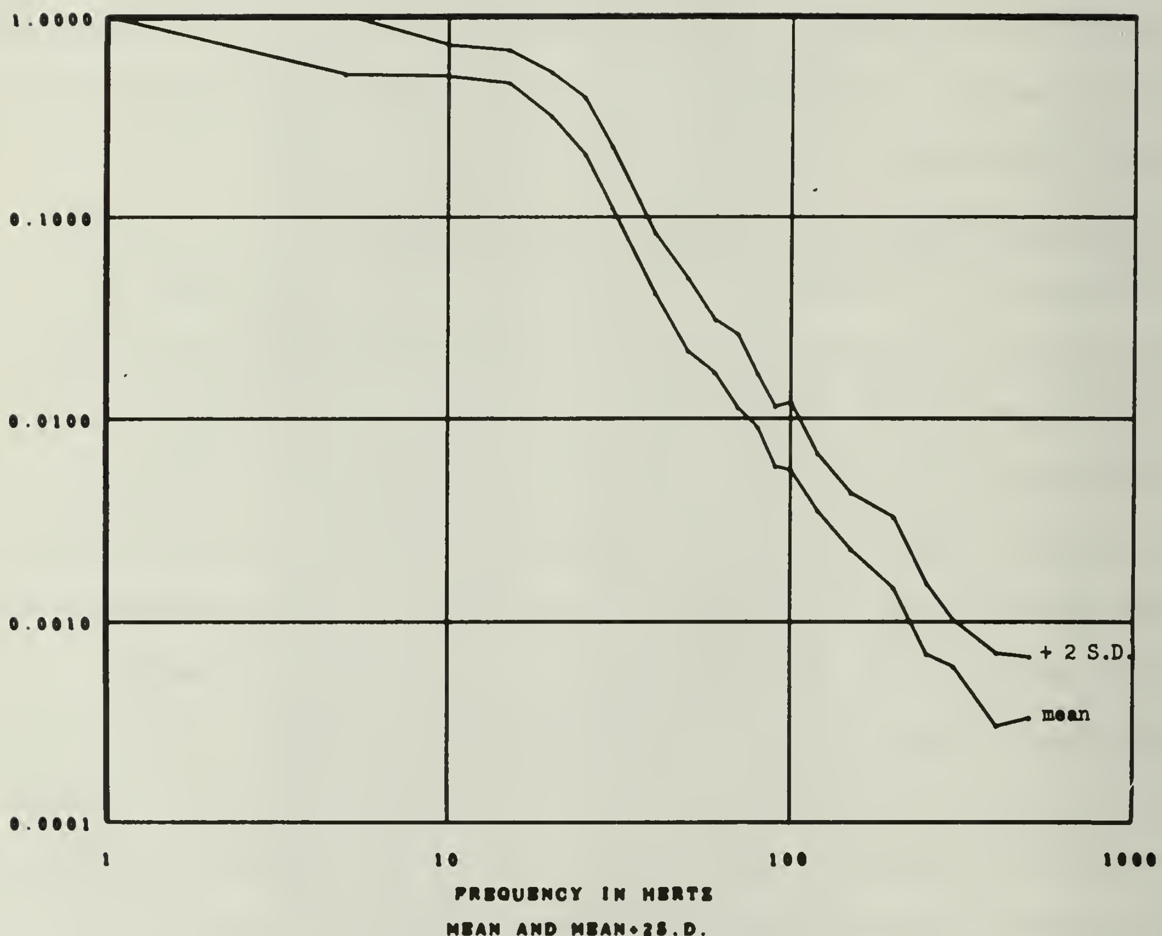


Figure 12. Plot of Mean Frequency Sprectrum of ECG's of 10 Subjects [11].

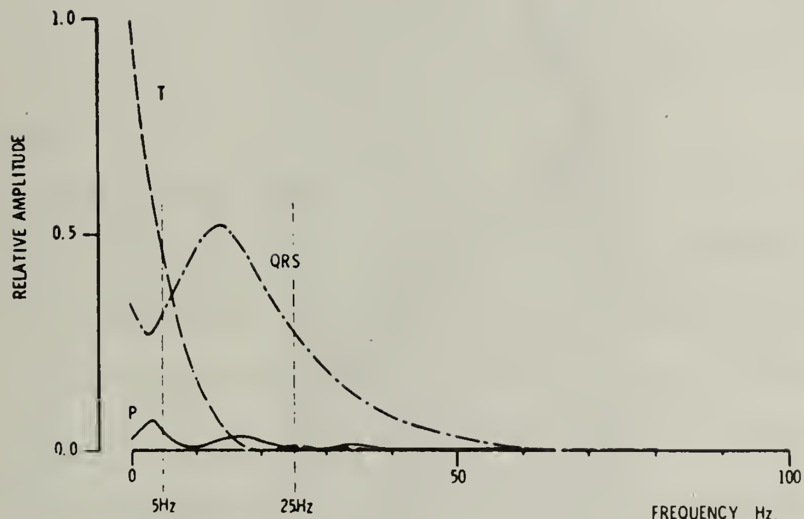


Figure 13. Power Spectrum of Typical P, QRS, and T Waves [12].

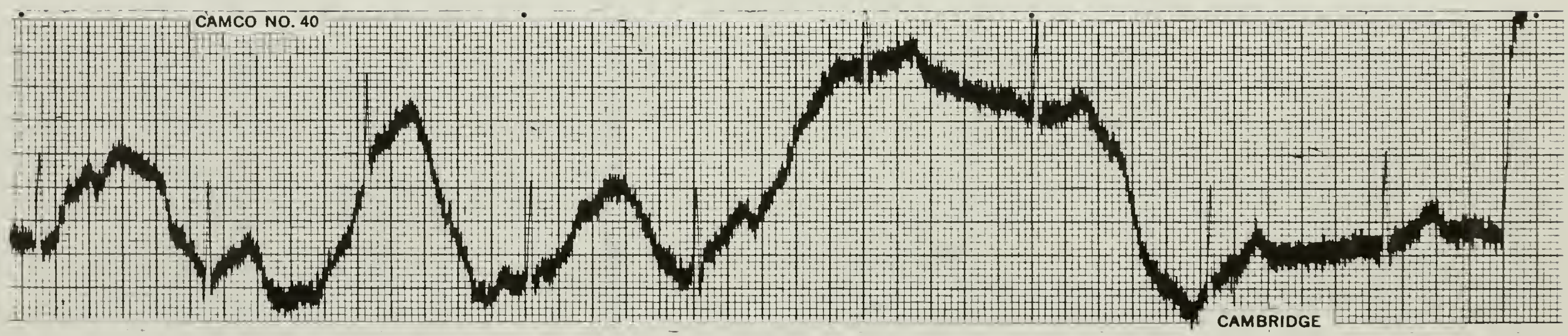


Figure 14. Example of a Noisy ECG.

3.2 Mathematical and Frequency Analysis Approach

A PVC is usually recognized by its two characteristics, namely, its prematurity and its bizzare wave shape. One or both of these characteristics are often employed to detect PVC's. The following summarizes some of the approaches developed.

3.2.1 Matched Filter Approach

One natural choice of methodology is to build a carefully tailored, matched filter - an approach adopted by Feezor et al [13]. The matched filter is realized by a cascade of 10 third-order analog delay filters having a total delay of 350 msec. The impulse response of the filter is approximately that of a time reversed PVC waveform. When a PVC passes through the filter, high correlation is obtained.

3.2.2 Phase Detection of R Waves

By using the relationship of the phase angle and frequency of the QRS complex, Amazeen, Moruzzi and Feldman [14] reported very accurate determination of RR intervals to within ± 1 percent accuracy. Their approach looks at each QRS complex as approximately a time function with even symmetry at t=0 point. The ECG is Fourier transformed, its phase angles are plotted against the frequencies. The time of occurrence of R peaks are then determined from the slopes of the plot.

3.2.3 Heart-beat Interval-Markov Chain Approach

A "heart-beat Interval-Markov Chain" approach was employed by Gersch, Eddy, and Dong [15] at Stanford University in which a sequence of RR intervals is automatically transformed into a Markov chain sequence. The probabilities that the observed sequence was generated by each of a set of prototype models of arrhythmias are calculated. The prototype corresponding to the highest probability confirms the type of the arrhythmia.

The foregoing procedures are only examples of the work done in the field of arrhythmia detection by means of frequency analysis and various mathematical tools.

3.3 Feature-Extraction Analysis of ECG

This represents a widely adopted approach to ECG analysis. This approach employs the direct timing, duration, and shape information of the waveform, individually or altogether, to infer the nature of the waveform. Both digital, analog, and hybrid systems have been realized for the analysis. With the lack of standardization regarding system evaluation, it is impossible to judge which system is the best. However most of the systems developed today use digital techniques.

There are several approaches to determine the QRS morphology. All of these rely on the fact that the QRS occupies the high end of the ECG frequency spectrum and the R-S slope contains the highest frequency spectral components. Noises, regardless of their origins, normally do not have the long duration as the R-S slope.

In an approach adopted by Fitzgerald, Clappier, and Harrison [16] at Stanford, a filter is used which passes only the highest frequency components of the R-S slope. The output of the filter triggers processing of the ECG signal. RR interval, QRS duration, and the area under the QRS are calculated. Arrhythmias are identified by noting any variation in these parameters from the normal sinus rhythm.

A similar approach used by Neilson [17] at the University of Edinburgh integrates the difference between the incoming QRS and a norm. This difference is then compared with a threshold to determine its nature.

A third approach as employed by Horth [18] at Hewlett Packard first differentiates the input waveform which has been normalized by analog circuitry. Since the QRS complex has the highest gradients in the ECG, only its slopes can overcome a preset threshold for a minimum duration of time. The latter constraint allows the detection of R peaks while eliminating false triggering by noise. The RR duration and QRS width can henceforth be calculated which together allows the detection of arrhythmia.

All of the digital systems [1, 9, 14, 20-28] reported thus far applied digital differentiation of the ECG. The input waveform is sampled at 200 to 500 samples per second. First or second differentiation is obtained by simply subtracting sample values at fixed intervals. The differentiated value is compared to a threshold for the location of QRS complex. Detailed discussion will be presented in the system consideration of Cardalert which uses this approach. Several large systems are developed using digital techniques. For example, Aztec is a large system developed by Cox, Nolle, and Fozzard [1, 13, 19]. Ninety percent accurate detection of PVC's has been reported with this system. Systems developed at the Latter-day Saints Hospital, Salt Lake City; and the Thorax Center in Rotterdam are also examples of the numerous digital systems developed. Satisfactory performance are produced by all of them. Unfortunately one drawback common to all of these systems is that they are all software-oriented employing large computer systems for analysis. Accurate performance is obtained but they contribute little to producing alarms for potential heart attacks which occur outside hospitals, which is, of course, the problem which the present work addresses.

4. CARDALERT

Digital differentiation technique has been adopted in Cardalert for R detection. Multiple processors are used to achieve data reduction, thus minimizing storage requirements. In the block diagram shown in Figure 15, the main Cardalert unit consists of a data acquisition unit for on-line, real time analysis, a preprocessor which performs feature extraction of the ECG, the RR processor and the QRS processor to analyze the RR interval and the QRS duration respectively, and finally an alarm system. An external adaptor for off-line ECG tape analysis at 60 times the real time rate can also be attached to Cardalert.

4.1 The Data Acquisition Units

Two data acquisition units designated as real-speed unit and tape-speed unit are used. Real-speed unit, as depicted in Figure 16, is used in real time analysis. ECG signals from lead II skin electrodes are amplified by a differential amplifier which has a very high common mode rejection ratio. This rejects most of the noise simultaneously present in both electrodes. In general, the desired ECG signal is as small as 0.5 mv for the P wave and about 1 to 2 mv for the QRS complex, all embedded in noise as large as 100 mv. The differential amplifier also provides a gain of 5000. The amplified signal is then fed into a bandpass filter which consists of a high pass filter and a low pass filter with corner frequencies at 0.5 Hz and 40 Hz respectively cascaded together. The circuit diagrams of the amplifier and the filter are shown in Figure 17. The filter stage further reduces noise associated with the ECG, especially 60 Hertz and baseline drift noise. After filtering, the relatively noise-free ECG is digitized into 8-bit data streams at 250 samples per second for further analysis. The sampling speed of 250 sps has been chosen as a compromise between adequate sampling rate and the amount of hardware required.

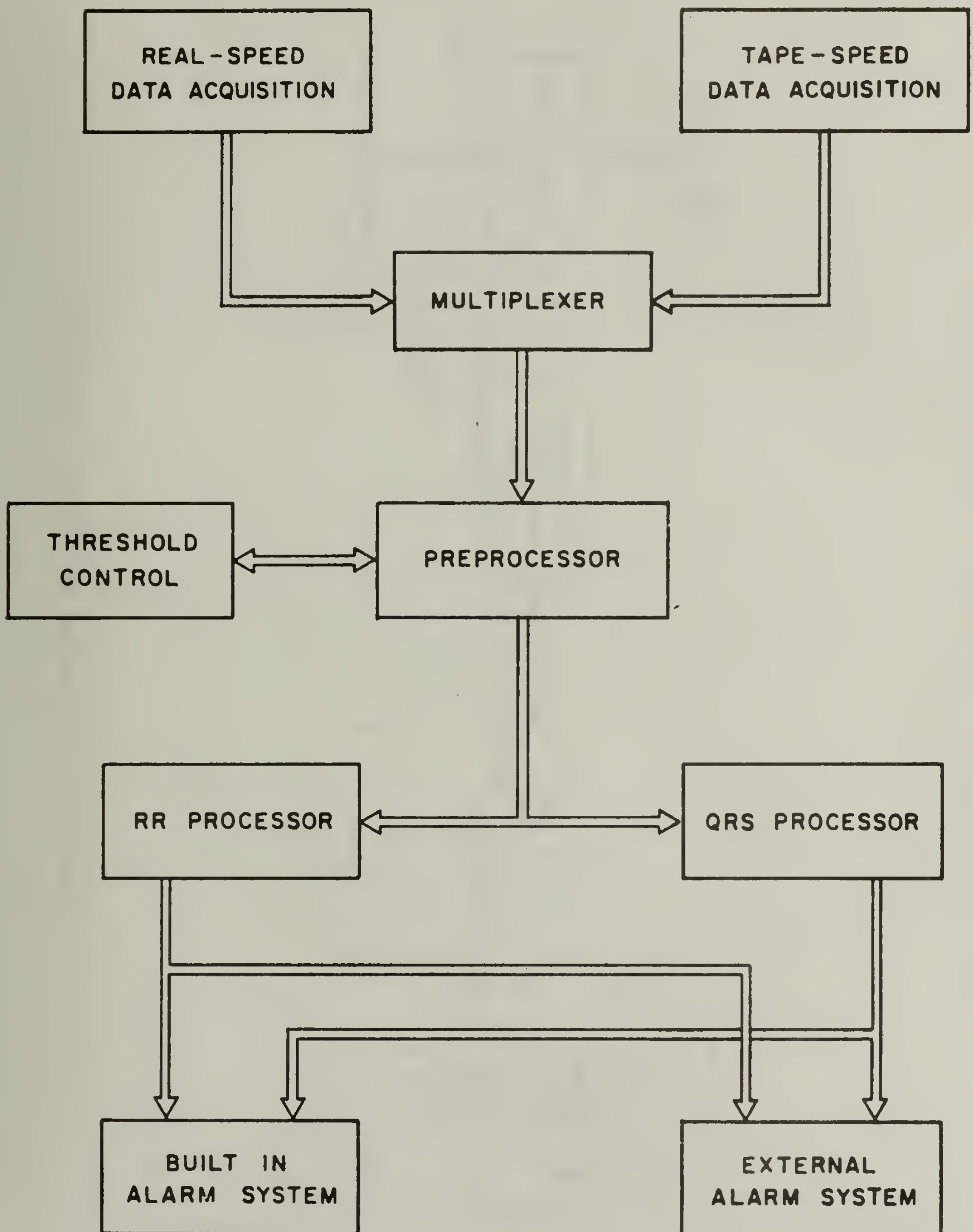


Figure 15. Cardalert Block Diagram

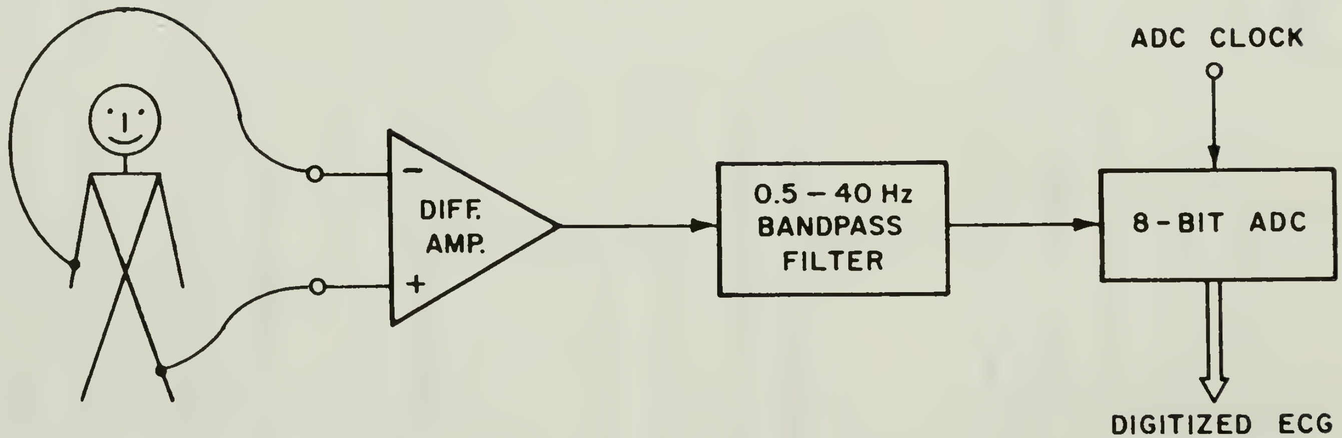


Figure 16. Real-speed Data Acquisition Unit.

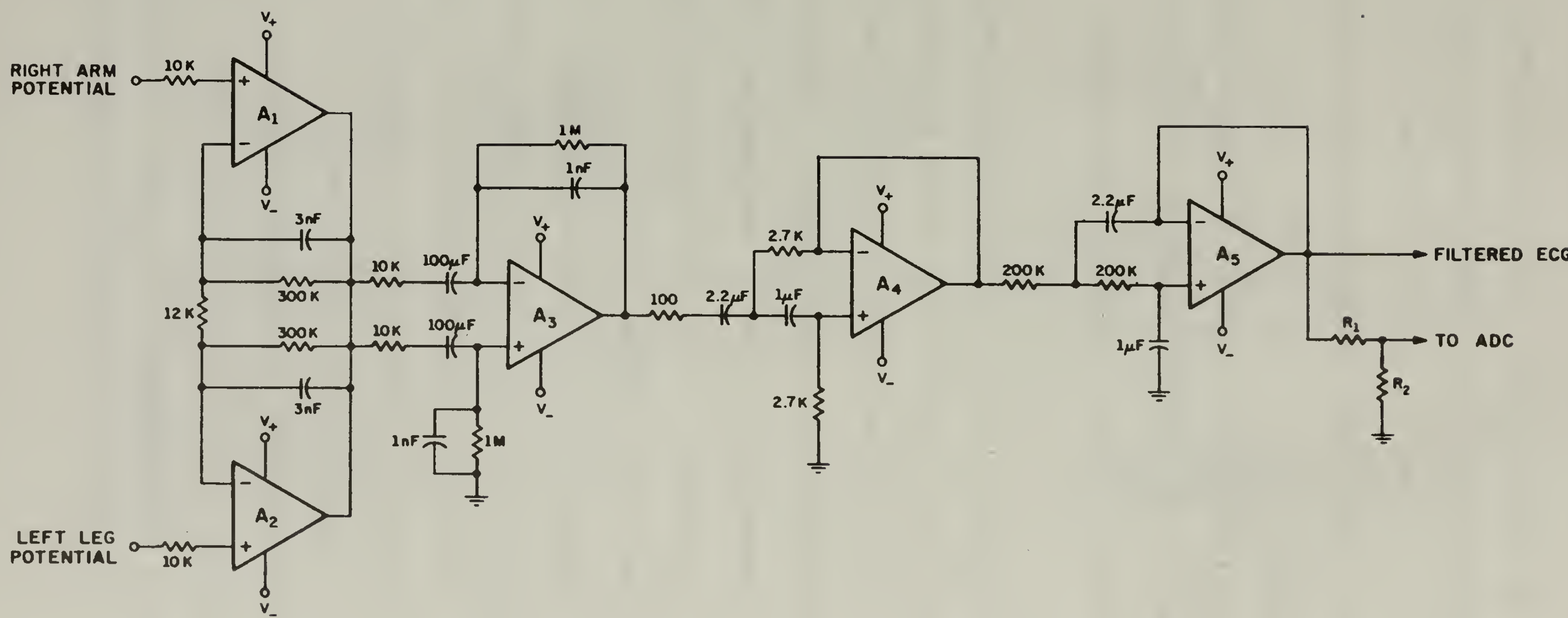


Figure 17. Circuit Diagram of the Differential Amplifier and Bandpass Filter for Real-Time Operation.

Tape-speed data acquisition unit (Figure 18) allows Cardalert to analyze ECG tapes at sixty times real time speed. A standard tape deck plays back the tape at 7 1/2 inches per second (60 times the recording speed of 7 1/2 inches per minute). An amplifier amplifies the signal which is then converted into 8-bit sequences at sixty-times the original sampling frequency (60 x 250 = 15,000 sps). A bandpass filter is not used in the prototype but is conceived as very helpful for more accurate analysis.

The selector for either mode of operation is simply a mechanical connector which connect (disconnect) the desired (undesired) signal into Cardalert. Pictures in Figure 19 and 20 clearly demonstrate the two modes of operation.

4.2 The Preprocessor

It was shown earlier that the QRS occupies the upper portion of the frequency spectrum and has the steepest slope in the R-S portion of the ECG. Thus the R peaks are easily located by choosing an appropriate slope-threshold such that only the QRS complex would have slope values greater than it. In order to avoid errors caused by noise that escaped earlier filtering and have slopes greater than the threshold, a further constraint can be imposed by requiring a minimum duration of the slope.

The algorithm is shown in the block diagram of Figure 21. Incoming signals are differentiated digitally by simply subtracting the present sample value from the previous value. If this first difference is positive, it implies a negative slope and its value is compared with the <u>negative-slope threshold</u>. If the first difference is negative, it corresponds to a positive slope. Its absolute value is compared with the <u>positive-slope threshold</u>. Whenever the first difference is greater than the threshold, positive or negative, it is called a candidate (specifically, a <u>NS candidate</u> if it happens on the R-S slope and <u>PS candidate</u> if it is on the Q-R slope where NS and PS stand for negative slope

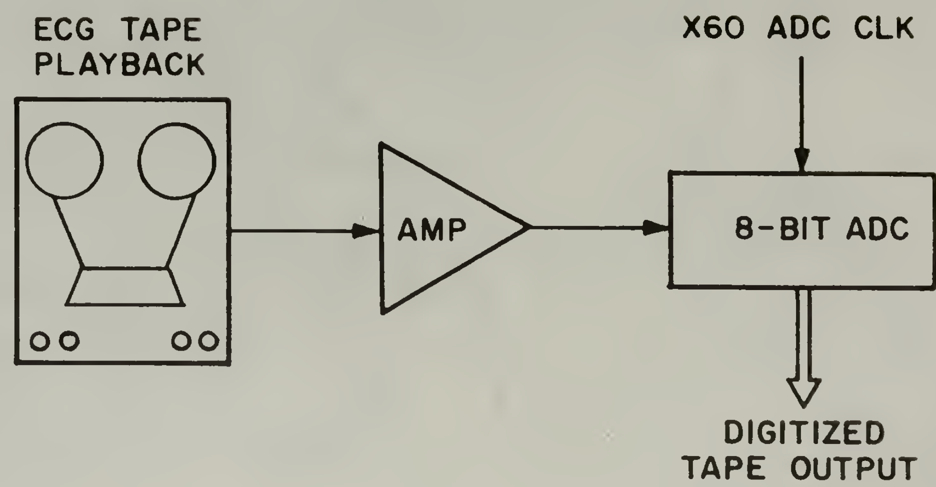


Figure 18. Tape-speed Data Acquisition Unit.

Figure 19. Picture Showing Real-time Operation of Cardalert.

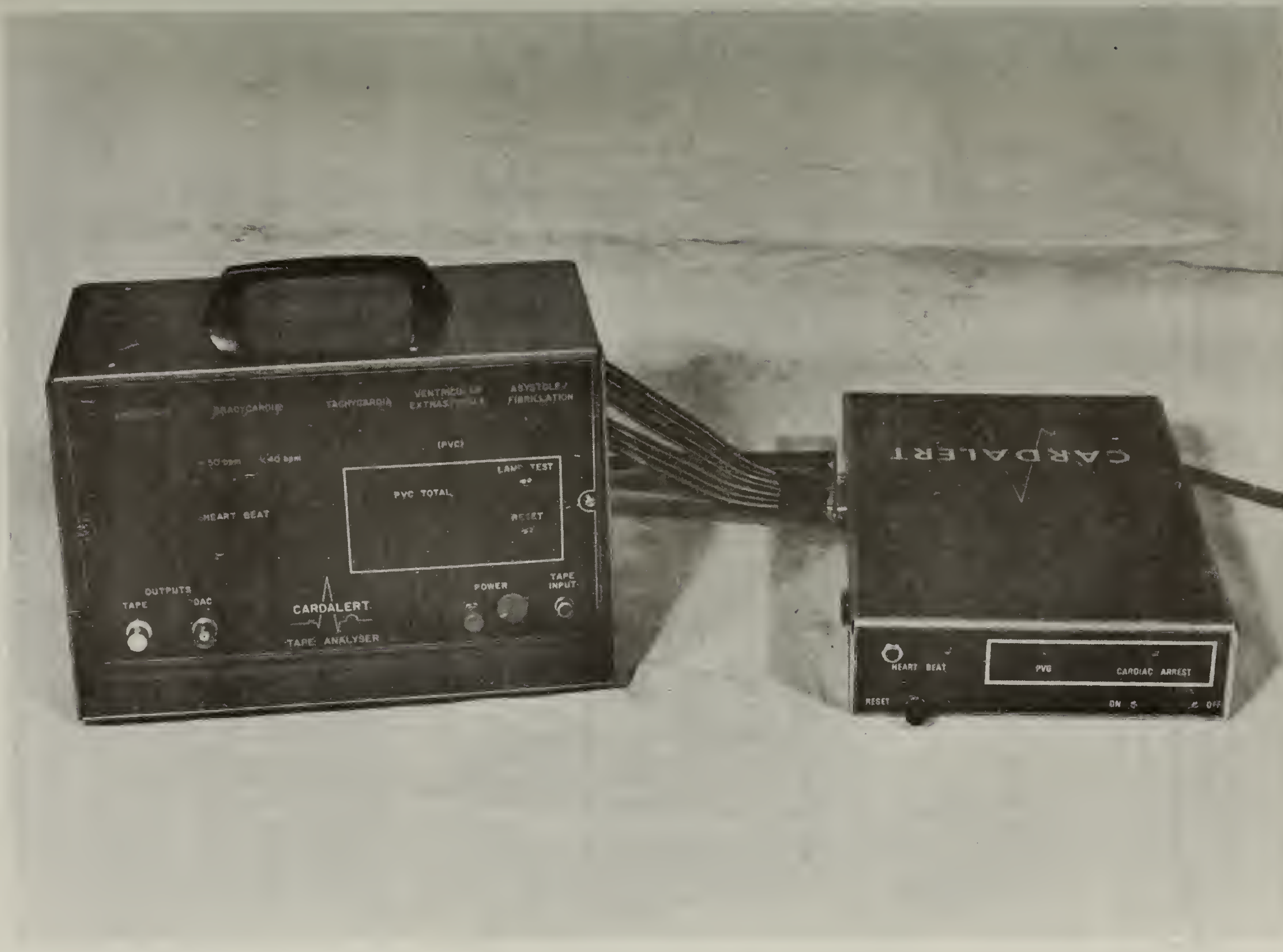


Figure 20. Picture Showing 60-times Real-time Speed Operation of Cardalert.

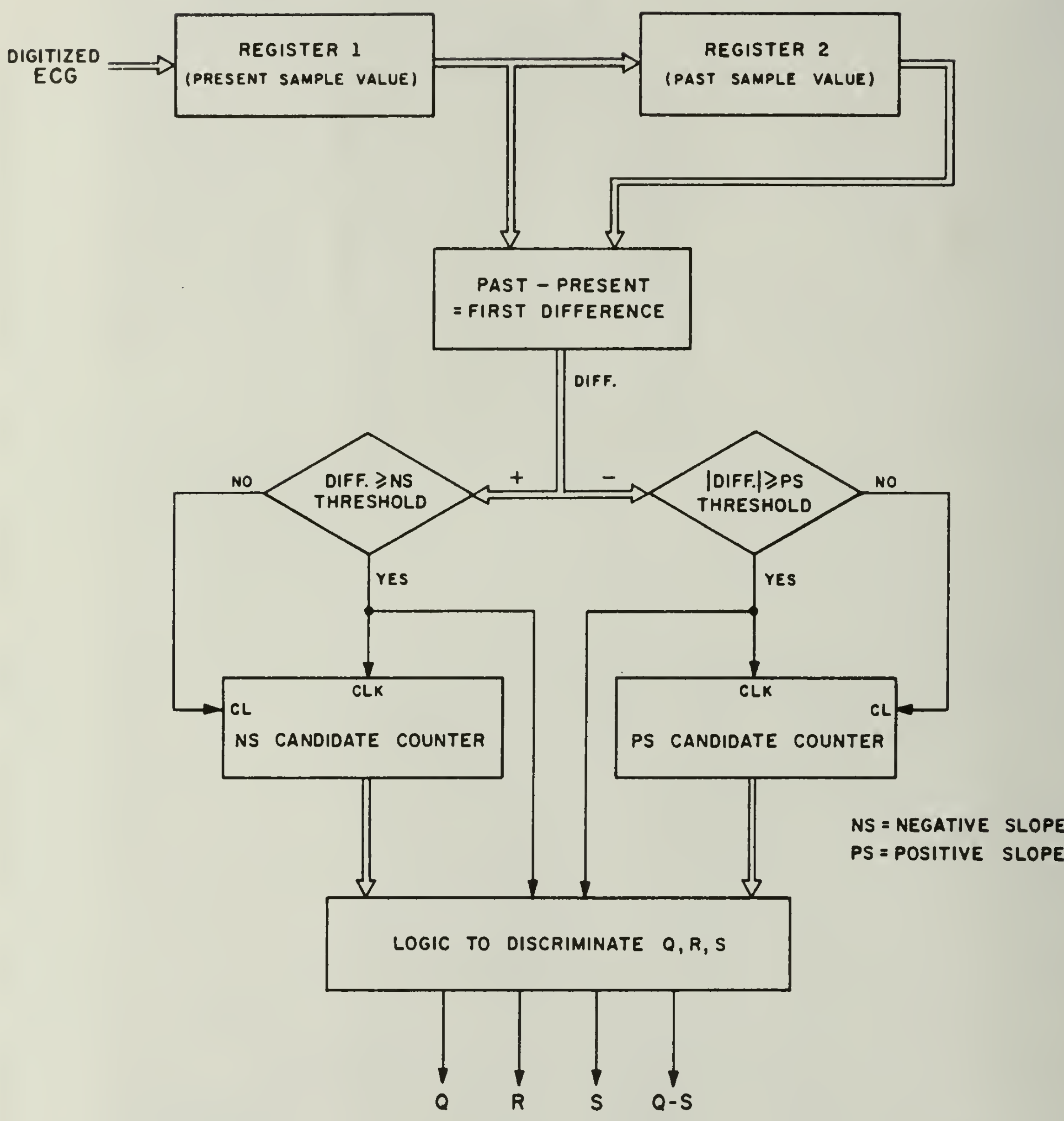


Figure 21. Block Diagram of the Preprocessor.

and positive slope respectively). As pointed out earlier, the negative R-S slope is steeper and longer in duration than the positive Q-R slope of the QRS; therefore the R-S slope is used in identifying the QRS because this allows a higher threshold value and hence smaller chances of false detection triggered by noise. To find out the minimum duration requirement, it is noted from the ECG frequency spectrum that the QRS is essentially confined in the 5 - 35 Hz bandwidth [12]. Using the upper limit of 35 Hz, it is estimated that one cycle of a 35-Hz sinusoid has a measurable downslope of approximately 12 msec. At a sampling rate of one per every 4 msec., this implies a minimum of three consecutive candidates. Since ECG's from different persons differ and there is even no assurance that ECG wavetrains are equal for one individual, an adaptive threshold is used which constantly adjusts the threshold into some mean or midpoint value. In order to keep the number of candidates within reasonable limits, an upper limit on the number of consecutive candidates is calculated. Since a minimum QRS duration is 60 msec., approximately half of that, 30 msec. is assumed for the R-S downslope. At the sample rate of 250 sps, it allows for seven consecutive candidates. Thus the range of consecutive candidates is limited to lie between three and seven.

Therefore when three to seven consecuitve NS candidates are recorded, a R peak is confirmed. A similar algorithm allows the machine to locate the Q of the QRS complex. Since abnormal QRS may sometimes be reversed in polarity due to its ectopic origin and abnormal conduction path, extra logic is needed for reliable recognition of QRS's of either polarity. At the detection of a possible Q or R, a window of 256 msec. is allowed for the occurrence of R or Q respectively. If both events occur during this time interval, the first

point is regarded as Q and the second one the R, regardless of their polarities. However, if the second point is not detected during the designated time, the first point is disregarded. S is located by noting the point at which it first fails to produce a candidate after a Q and an R were both confirmed.

4.3 The Adaptive Automatic Threshold Control

In order to establish a reliable threshold that is adaptive to the individual, an adaptive automatic threshold control unit as shown in Figure 22 is incorporated into the preprocessor. It consists of a NS threshold counter and a PS threshold counter for establishing the negative-slope threshold and the positive slope threshold respectively. When the machine is first turned on, the NS-threshold counter is initially set at a value of 00001111 and the PS threshold counter at 01110001. The value 00001111 is chosen because it was found experimentally that the NS threshold was always below this value. Therefore, one four-bit counter is used for the least significant bits only when the most significant four bits of the threshold are hard-wired to zeros. Similarly, only one four-bit counter is actually used for the PS threshold counter, and the value 01110001 is the two's complement of 00001111 except for the first bit. (This relation is not rigorously true but is found to produce a satisfactory result at present. The initial value of either threshold counter can be programmed by the operator.) After a preset time delay allowing all the flip-flops, registers, and memories to clear, the value of the NS threshold is decremented at a rate of 1 Hz until three consecutive candidates are produced. The value of the NS threshold counter then corresponds to the maximum threshold value for that individual above which three consecutive candidates cannot be produced. Once this value is reached, the NS threshold counter stops counting down. When the next QRS occurs and brings forth another three consecutive candidates, the threshold is allowed to scale down by one.

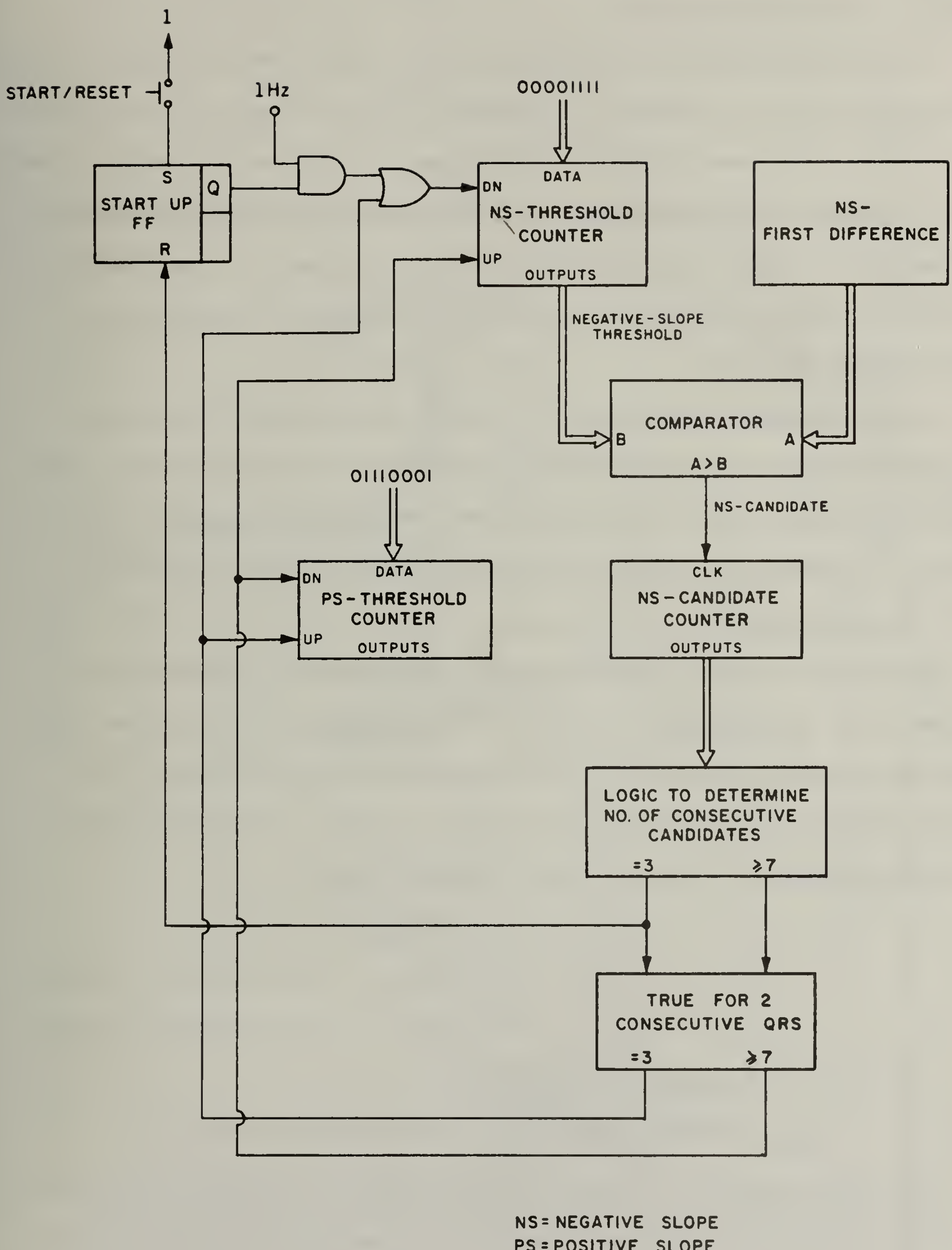


Figure 22. Block Diagram of the Adaptive Automatic Threshold Control.

The system seeks to make the threshold stay in the mid-range producing four to six consecutive candidates.

On the upper end, if two consecutive QRS's produce seven or more consecutive candidates each, the threshold is determined to be too small and is increased until fewer than seven consecutive candidates are produced by a QRS. To avoid false triggering by long duration noise with slope values greater than the threshold, the signal is disregarded whenever ten consecutive candidates are produced. Ten was arbitrarily chosen and can be modified according to experimental evidence.

The PS threshold is produced in a similar fashion, its value being incremented whenever the NS threshold is decremented, and vice versa. It does not directly affect the adjustment of the threshold counters since the R-S slope has the steeper gradient and is more reliable to work on.

4.4 The RR Processor

Whenever an R peak is detected by the preprocessor, it sends out a pulse to the RR processor indicating its occurrence. The RR processor takes this information, processes it, and determines if that particular R, or more precisely that particular RR interval, is normal. An RR interval is defined as abnormal by any of these three conditions:

(i) $RR \leq 0.8\ RR_{avg}$

(ii) $RR \leq 600$ msec. i.e. heartbeat > 120 bm

(iii) $RR \geq 1.2$ sec. i.e. heartbeat < 50 bm

where: RR = the present RR interval

RR_{avg} = average of previous four normal RR interval.

The block diagram of the RR processor is shown in Figure 23. To test for condition (i) which implies that the QRS is premature, the processor has to keep a value equal to 80 percent of the running average of the normal RR intervals.

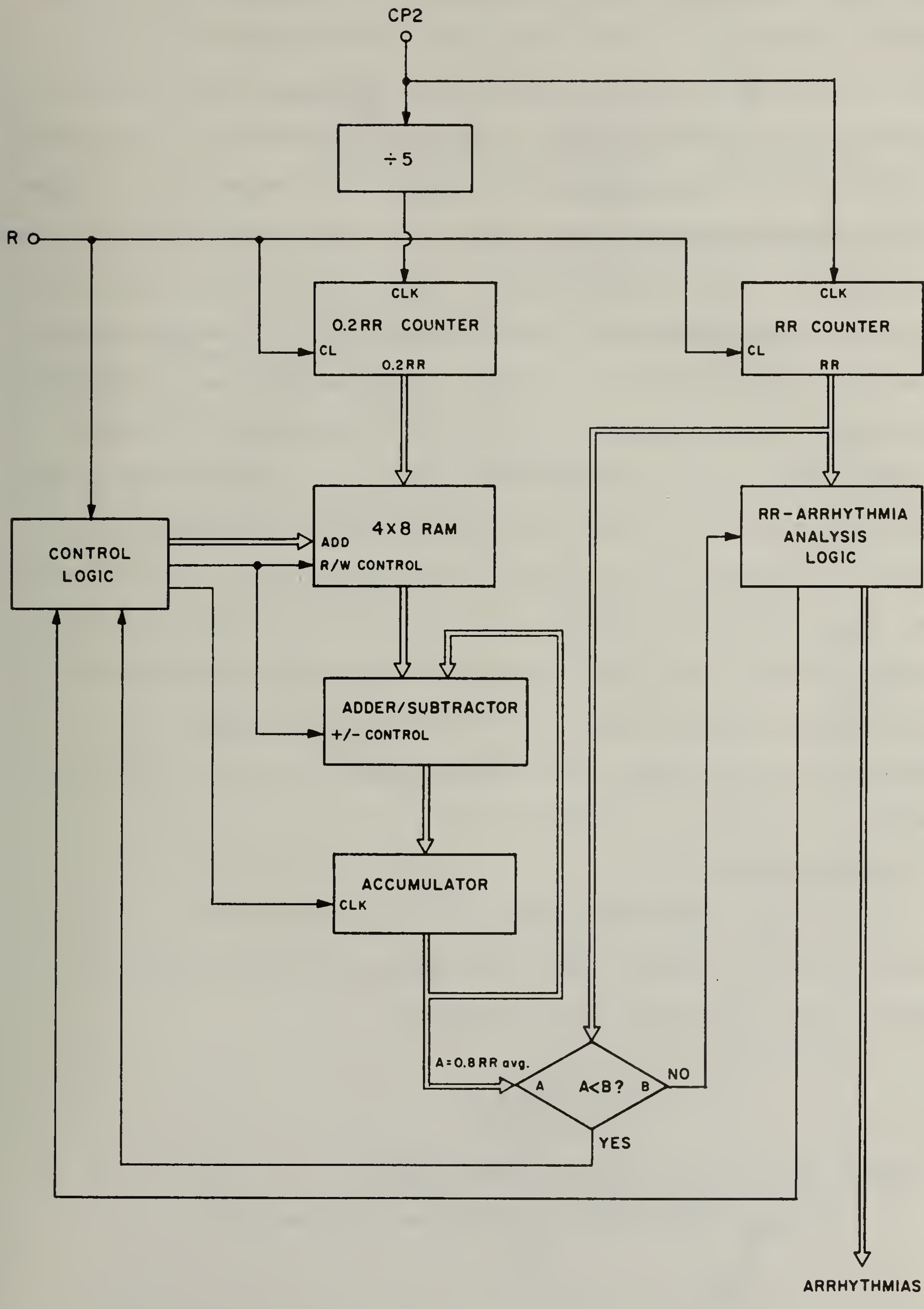


Figure 23. Block Diagram of the RR Processor.

This is done by a counter - the 0.2 RR counter, which divides all RR intervals by five. Whenever an R is identified, its time interval with respect to the previous R is recorded in another counter - the RR counter. This RR value is compared with the present 0.8 RR_{avg} to test against condition (i). Conditions (ii) and (iii), which imply bradycardia and tachycardia respectively, are also tested by the RR-arrhythmia analysis logic block. This block is built with simple combination circuitry. If any arrhythmic condition is detected, a signal is fed into the control logic which immediately interrupts the averaging scheme and neglects this particular RR duration. If a normal RR interval is recorded, the value in the 0.2 RR counter is written into a circulating 4 x 8 memory. The memory address is then updated and its contents are added together to yield the 0.8 RR_{avg} value. This value is then refreshed into the accumulator to be used as a reference to test the next incoming RR interval. If the next R is normal again, the oldest 0.2 RR value in the memory is subtracted from the accumulator content. It is then replaced by the new 0.2 RR interval and a new 0.8 RR_{avg} is calculated again. If condition (i) is detected, it is combined with the test result from the QRS processor to confirm if a PVC has occurred.

4.5 The QRS Processor

Two approaches for the QRS processor were tested experimentally based on different definitions of PVC. Their block diagrams are shown together in Figure 24. In the first one, PVC is defined as:

(i) $RR \leq 0.8\ RR_{avg}$

(ii) $QRS > 1.25\ QRS_{avg}$

where: QRS = the duration of the QRS complex

QRS_{avg} = the average of four normal QRS durations.

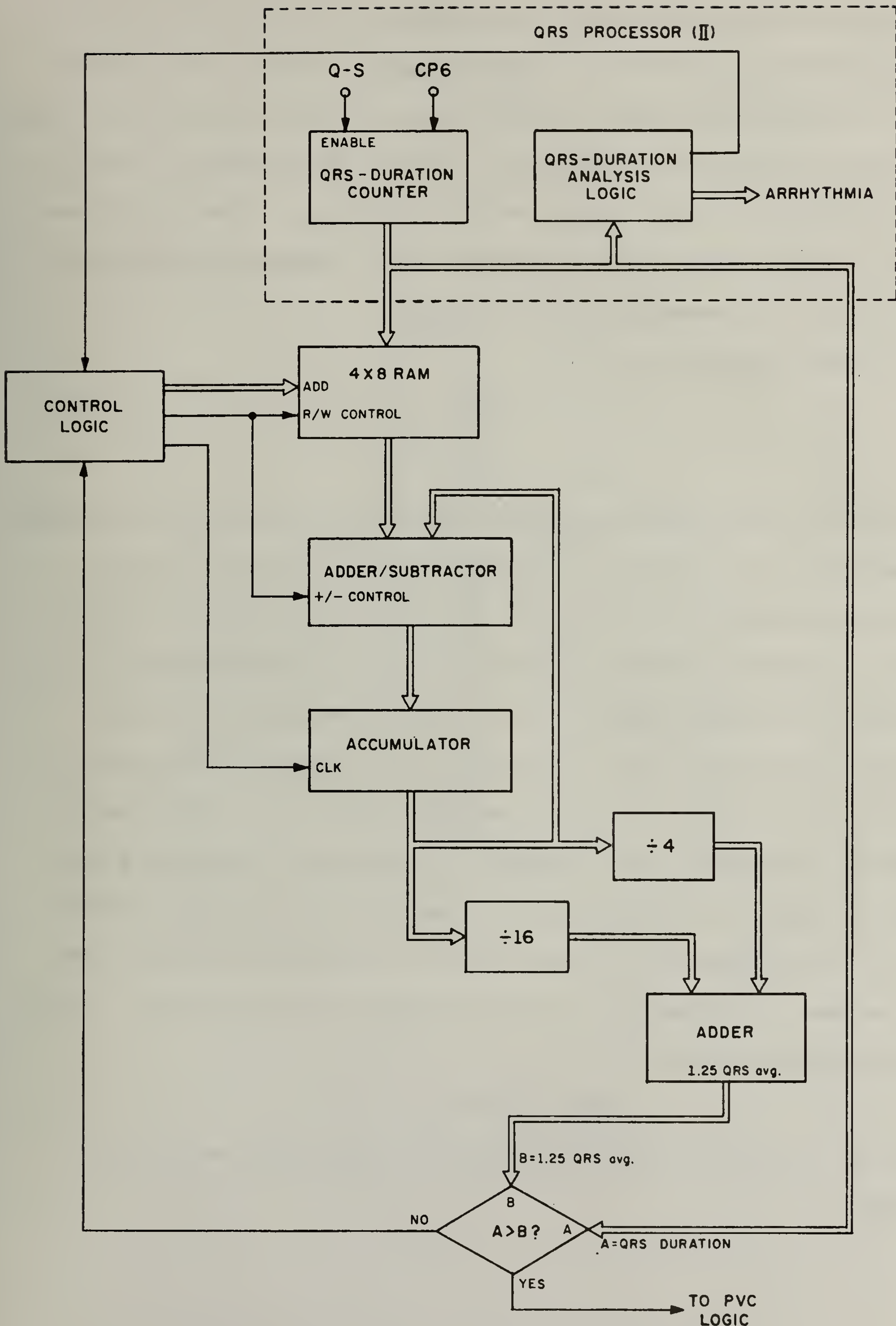


Figure 24. Block Diagram of the QRS Processor.

The first condition is detected by the RR processor just described. The second condition is processed by the QRS processor. Similar to the RR processor, the QRS processor keeps a running average of four QRS durations. Normal QRS values are stored in an accumulator. Dividing the accumulator value by four and sixteen and adding again gives the 1.25 QRS_{avg}. Incoming QRS's are compared to this value to test for condition (ii). Abnormal QRS durations are not used in the averaging process.

The second definition of PVC is

$$\text{(i)}\quad RR \leq 0.8\ RR_{avg}$$

$$\text{(ii)}\quad QRS > 0.1\ \text{sec}$$

This definition has one great advantage over the first one in that the hardware implementation is a lot simpler. Its block diagram is enclosed by the dotted line in Figure 24. A counter to keep track of each QRS duration is all that is required. However it should be noted that the QRS duration described in this thesis does not have the same connotation as the usual definition of QRS used by most other literatures. Normally, QRS duration is defined from the onset of ventrucular activity to the end of depolarization whereas the QRS duration here is referred to the positive deflection alone, as shown in Figure 25. This special QRS duration will be referred as QRS*. To utilize the definition of PVC given above, a corresponding value of QRS* has to be used. Unfortuantely, no published value of QRS* was found. It was found experimentally that if

$$QRS^* > 0.072\ \text{sec.}$$

is used to identify wide QRS, it provides satisfactory performance of PVC detection.

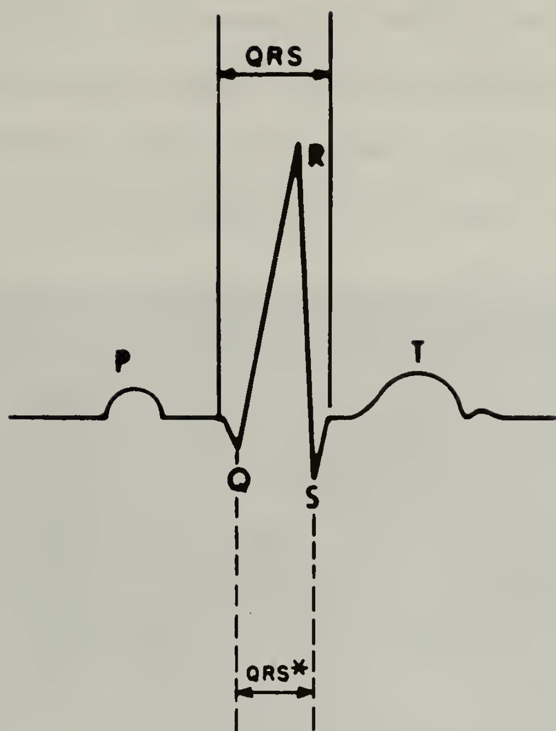


Figure 25. Definition of QRS*.

5. SYSTEM EVALUATION AND CONCLUSION

Actual statistics on the performance of Cardalert is not available at the time of this thesis. A carefully designed evaluation scheme has to be implemented in order to give a reliable study on its performance. Since no standardized ECG waveforms and arrhythmias are available, comparisons between performance data of different systems are impossible. Additionally, the performance of any system might be biased towards some particular waveforms used in the development of the system itself. With these problems in mind and with a generally inadequate quantity of performance data, some of Cardalert's performance are summarized below.

5.1 The Filter

Figure 26 compares the unfiltered waveform with the filtered. Considerable baseline drift is apparent in the unfiltered signal. Sixty Hertz noise is reduced in the filtered signal. The QRS complexes are slightly distorted but this does not interfere with the performance of Cardalert.

Heavier filtering is possible to produce a more noise free ECG, which is especially desirable since Cardalert is designed to be worn and used by people while carrying out their daily activities. The ECG would of course be more distorted by such a filter and a compromise must be worked out.

5.2 The Preprocessor

Figures 27 - 30 show the detection of R peaks by the preprocessor. Noises were intentionally introduced into the signal by the subject's movements and contact with noise sources. In Figures 27 and 28, the electrodes were intentionally moved by squeezing the hand and partially picking up the electrodes off the skin. In Figure 29, the arm with the electrode was waving feverishly to produce the baseline drift. Finally in Figure 30, considerable sixty Hertz noise appeared when the subject's hand was in contact with the

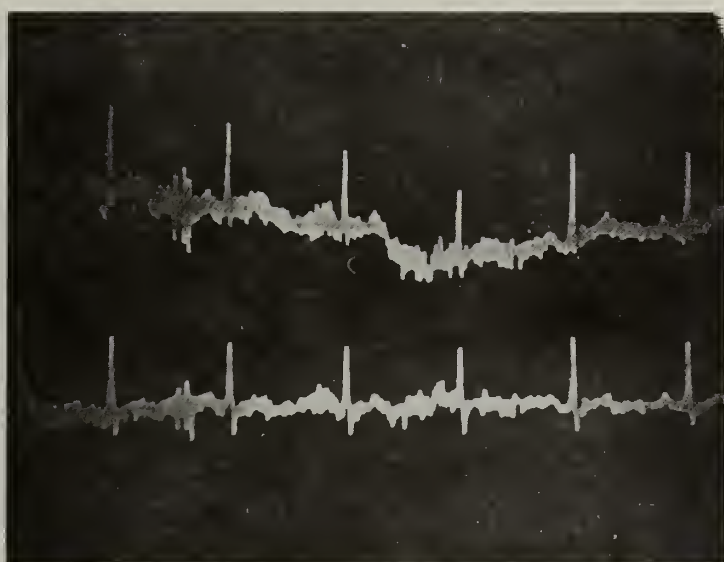


Figure 26. Unfiltered ECG (top) vs Filtered ECG (bottom).

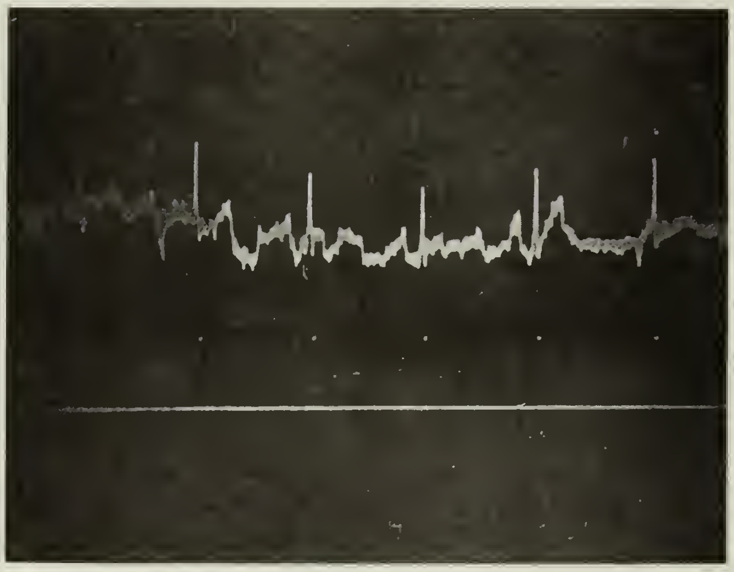


Figure 27. QRS Detection (note the artifacts produced by electrode movement).

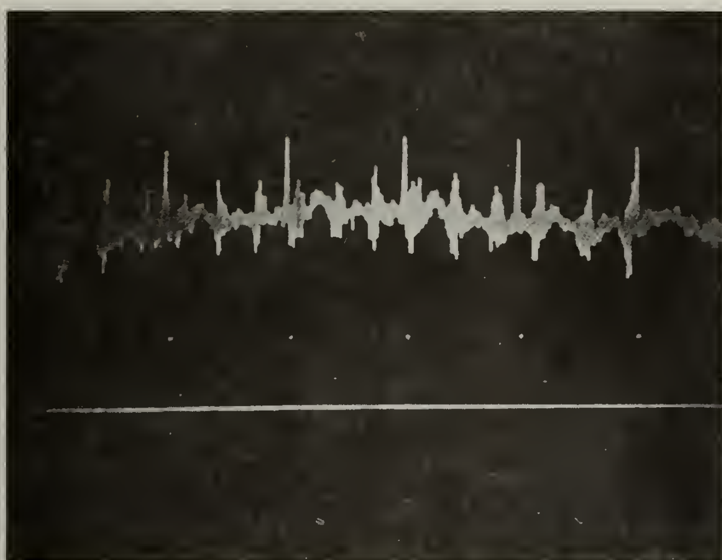


Figure 28. QRS Detection (note the artifacts produced by muscle movement).

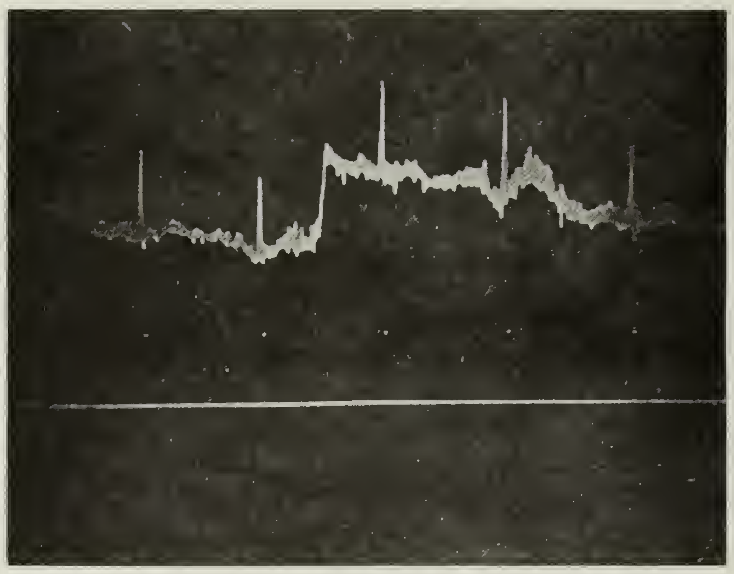


Figure 29. QRS Detection (note the baseline drift produced by waving the hand).

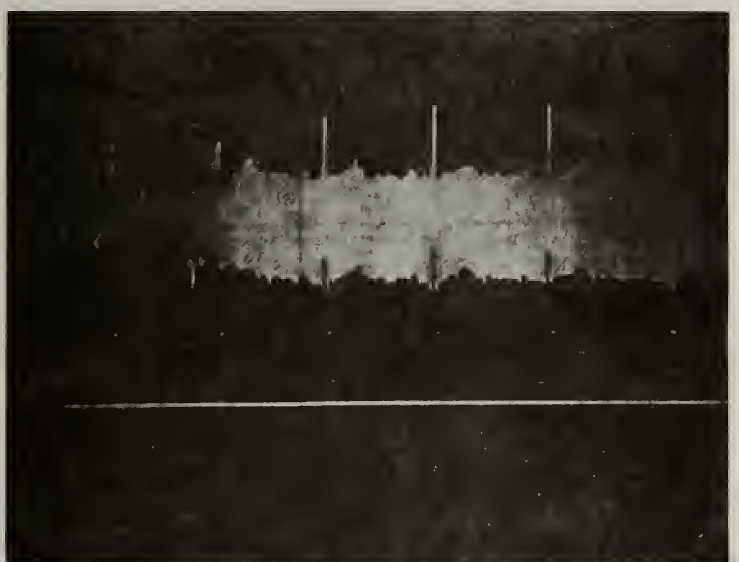


Figure 30. QRS Detection of ECG with Sixty Cycle Noise.

on/off switch of an ordinary table lamp with a two-prong AC plug. Reliable detection is demonstrated in all these pictures. Figure 31 was taken when Cardalert was operated at 60 times real time to analyze ECG tapes. Two false detections were triggered by noise with long negative slopes. The origin of the noise is unknown. However when at least ten consecutive candidates are produced by any slope, it is assumed as noise by the processors and subsequently disregarded.

5.3 The Processors

Figures 32 and 33 show two cases of PVC that appeared on a tape. Successful detection in both cases are indicated by the pulses which appear below the arrhythmias.

As mentioned earlier, two approaches were tried to implement the QRS processor. The first one detects wide QRS by the criterion:

$$QRS > 1.25\ QRS_{avg}.$$

There are basically two problems associated with this processor. The first one being the algorithm does not really produce 1.25 QRS_{avg} because the detection of Q is delayed by three samples corresponding to 12 msec. This value should be included in each QRS duration. The second problem which is causing most of the errors arise from the fact that QRS duration is measured in terms of numbers of samples or in units of four msec. Since a normal QRS produces about eight to ten samples (three less samples than the actual QRS as explained above), 1.25 of this small value plus the effect of truncation resulted from the circuit design makes the value of 1.25 QRS_{avg} to fall between ten to twelve. With the close proximity of these two ranges, a lot of false positives can occur depending on the initial start up of the machine. For example, if initially, the QRS values are equal to seven samples, 1.25 of this value gives eight as the 1.25 QRS_{avg}. The value seven is justified because the thresholds at the beginning tend to give the minimum number of candidates

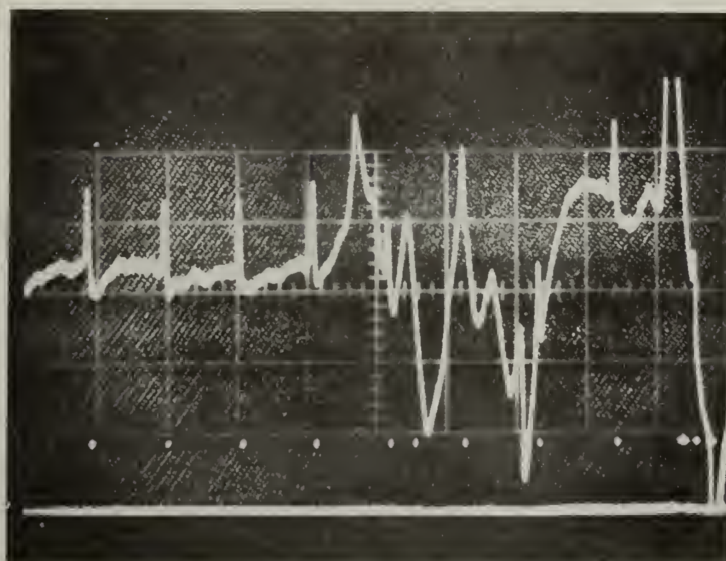


Figure 31. QRS Detection of a Noisy ECG Tape.

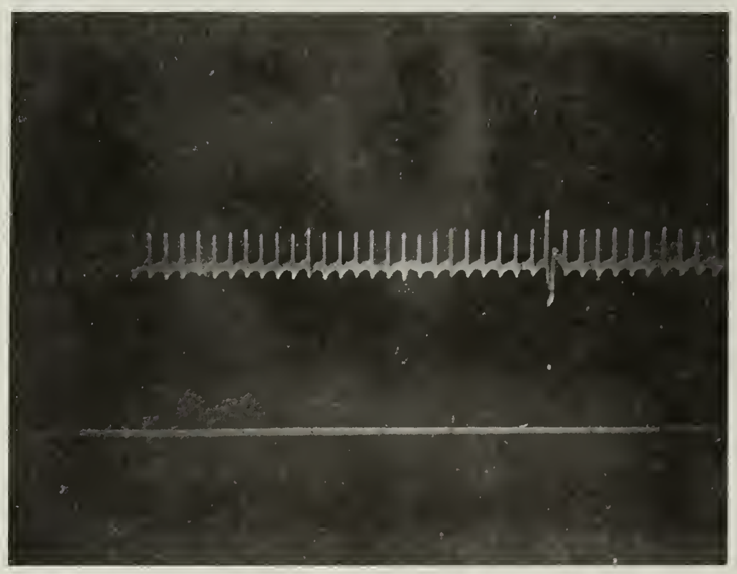


Figure 32. PVC Recognition by Cardalert.

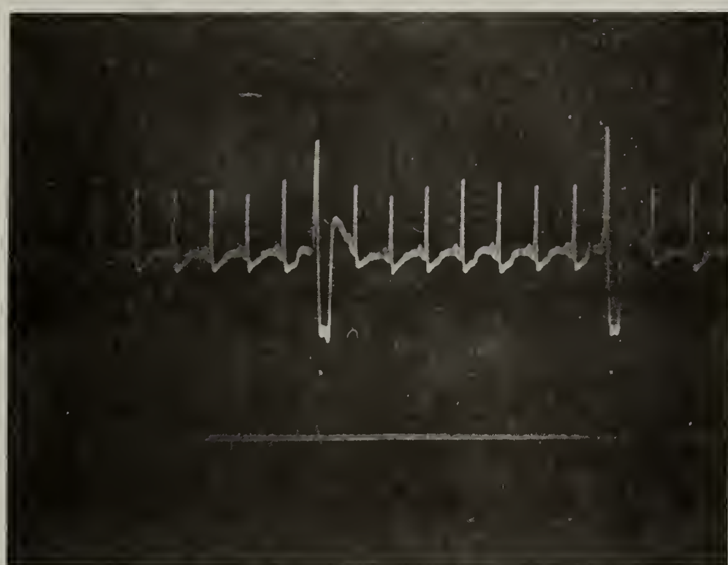


Figure 33. Another Example of PVC Detection.

as explained in the preprocessor section. As the thresholds are modified to lie in the mid-range, more samples for each QRS are recorded. But with this algorithm, all normal QRS complexes with more than eight samples would be viewed as widened thus producing erroneous classification. By delaying the averaging process of the QRS processor until the thresholds are settled in the mid-range gives less errors but the number of false positives is still considerable. Using higher sampling frequency thus giving finer resolution to QRS measurement would be helpful but this inevitably increases the memory size, counter size etc. and proportionally more hardware.

The second criterion for wide QRS is:

$$QRS^* > 0.072 \text{ sec.}$$

The problem with this criterion is that this relationship does not necessarily hold true for different individuals. One possible solution is to obtain a running average of the QRS* duration, if the new QRS* exceeds this running average by a preset amount of time (e.g. 12 msec.), it is defined as wide QRS*. This criterion has been successfully used by Horth [18].

The second criterion is used nevertheless, and the performance of Cardalert has been quite satisfactory.

A problem of a similar nature exists in the RR processor. Due to Compensatory pause or other physiological natures, or failure of Cardalert to detect a QRS, an exceptionally long RR interval can result. In the present scheme, its value is used in the running average regardless of its length so long as it is less than the upper bound of 1.2 second. Subsequent normal RR intervals may be viewed as premature because the RR_{avg} is now biased by the long RR and false alarms may result. Additional circuitry may be added to the system for it to neglect these long RR intervals. Since a PVC has to satisfy both the premature and wide QRS conditions, false alarms are minimal with the tapes tested so far.

5.4 Limitations of Cardalert and Conclusion

There are still several unsolved problems associated with the prototype Cardalert. One is concerned with the problem of loose electrodes. When that occurs, the cardiac arrest situation is alarmed. In real situations, cardiac arrest is a very dangerous state of heart condition, differentiation between the two conditions is almost automatic because the patient inevitably feels great discomfort and unconsciousness could possibly occur. Nevertheless, false alarms are very undesirable and an automatic loose-electrode detection should be incorporated into the system. A high frequency oscillator can be built into the machine so that it is activated whenever long periods without QRS are detected. The signal can be made to be transmitted through one electrode into the body, and picked up by the other electrode if continuity still exists. Different alarms then can be sent out corresponding to the different situations.

Another problem associated with Cardalert is concerned with its reliability under extreme noisy conditions. If sustained noise persists during the start up of the machine, the adaptive threshold can lock onto the the noise instead and produce erroneous threshold which would cause very unreliable performance of Cardalert. A noise detection scheme may be built into the system as was done by Geddes and Warner [28]. During the start up, noise level is detected and if excessive noise level is present, the machine is inactivated and automatically turned on again at a later time. This process is repeated everytime the machine is started until relatively noise free ECG is present to guarantee satisfactory threshold.

It should also be noted that Cardalert does not differentiate some supraventricular arrhythmias from ventricular arrhythmias. It also does not differentiate between cardiac standstill and ventricular fibrillation. Since the main function of Cardalert is to give premonitory warning on possible dangerous arrhythmias, detailed analysis of various other arrhythmias is not considered as important. However more thorough analysis can be done by accurately recognizing the P peaks and correctly estimating the baseline of the ECG.

No clinical performance of Cardalert has been tried up to this date. However, many hours of reliable Q,R,S identification in real time on a normal ECG has been recorded. Arrhythmia recognition has thus far been limited to 60 times real-time analysis of ECG tapes. Aside from some of the problems associated with the prototype discussed earlier, the performance of Cardalert has been very encouraging. Three batteries are required in this version of Cardalert, an unfortunate limitation imposed by the analog-to-digital converter. The machine consumes approximately 55 mW. of power. Assuming a battery life of 1000 mAH (e.g. the TR130 Series mercury batteries manufactured by Duracell) approximately 60 hours of operation can be expected.

To achieve real protability, miniaturization by means of customizing the circuits by a semiconductor house is a very attractive solution. Using a low power microprocessor such as the RCA CDP1802 CMOS microprocessor may provide some miniaturization in addition to flexibility of reprogramming. Information transmission of arrhythmia data through telephone lines is a means of patient, machine and medical personnel interface and should probably be considered in the next version of Cardalert.

Although there are still many problems to be solved, and improvements to be made, the technical feasibility of a portable arrhythmia detector which operates for several days on a set of batteries has been demonstrated.

Appendix

The circuit diagrams and timing schematics included herein contain the main working circuits and the timing relationship that make up the system of Cardalert. The following diagrams are included:

A1. System Clock Block Diagram and Timing Schematic

A2. System Clock Circuit Diagram

A3. Tape-Analyzer Amplifier and ADC Clock for X60 Real-Time Operation

A4. The Preprocessor Circuit Diagram

A5. Circuit Diagram of the Adaptive Automatic Threshold Control

A6. The Q, R, S Discrimination Logic Circuit Diagram

A7. The RR Processor Circuit Diagram

A8. The QRS Processor Circuit Diagram - version 1

A9. The QRS Processor Circuit Diagram - version 2

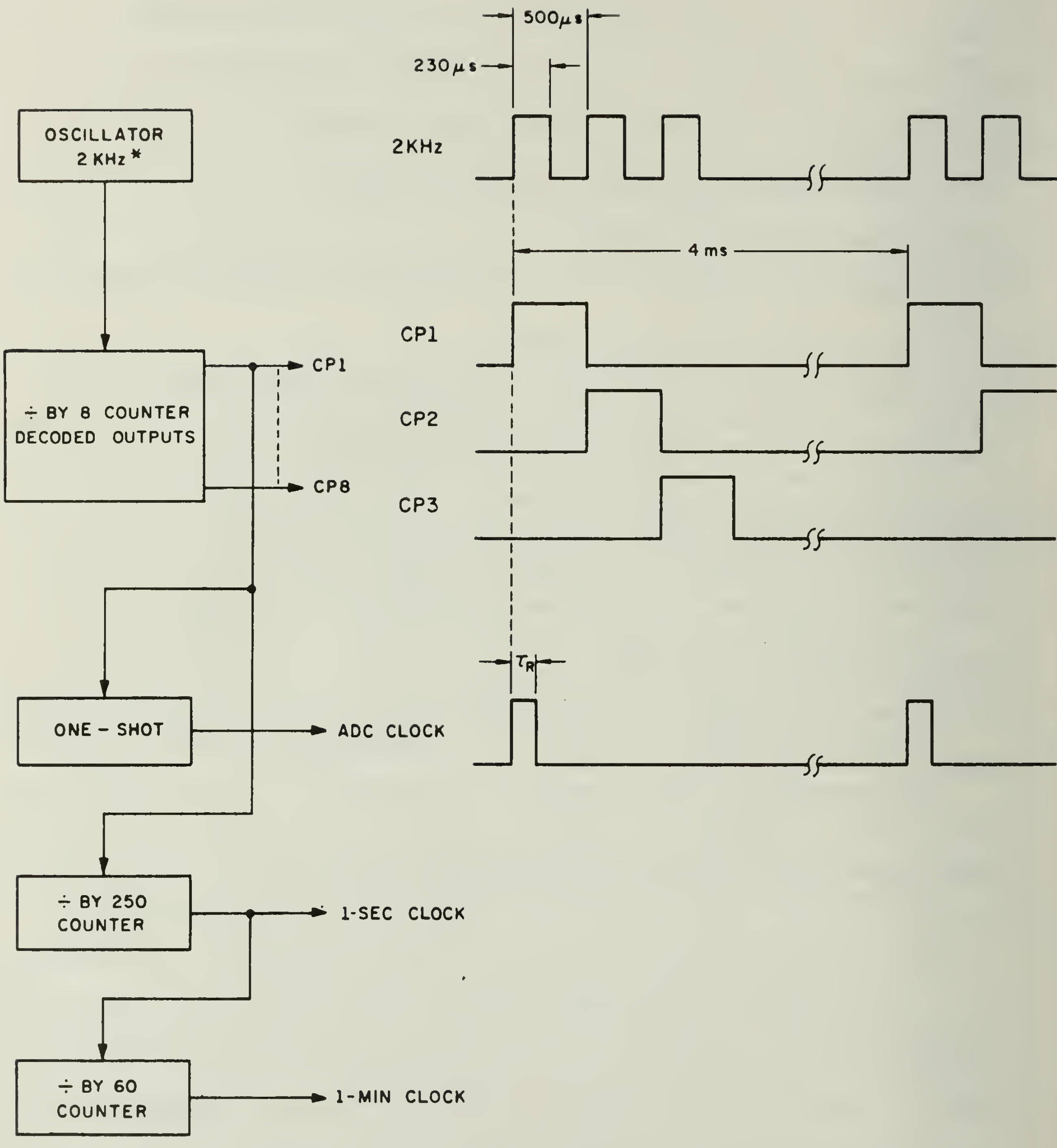
A10. PVC Alarm Circuit Diagram

A11. Heart Beat Simulator Circuit Diagram

A12. More Cases of PVC Detection

A13. Picture of Cardalert

A14. Front Panel of Cardalert Tape Analyzer Unit



* NOTE: MAIN CLOCK FREQUENCY = 120 KHz FOR X60 OPERATION

Figure A1. System Clock Block Diagram and Timing Schematic.

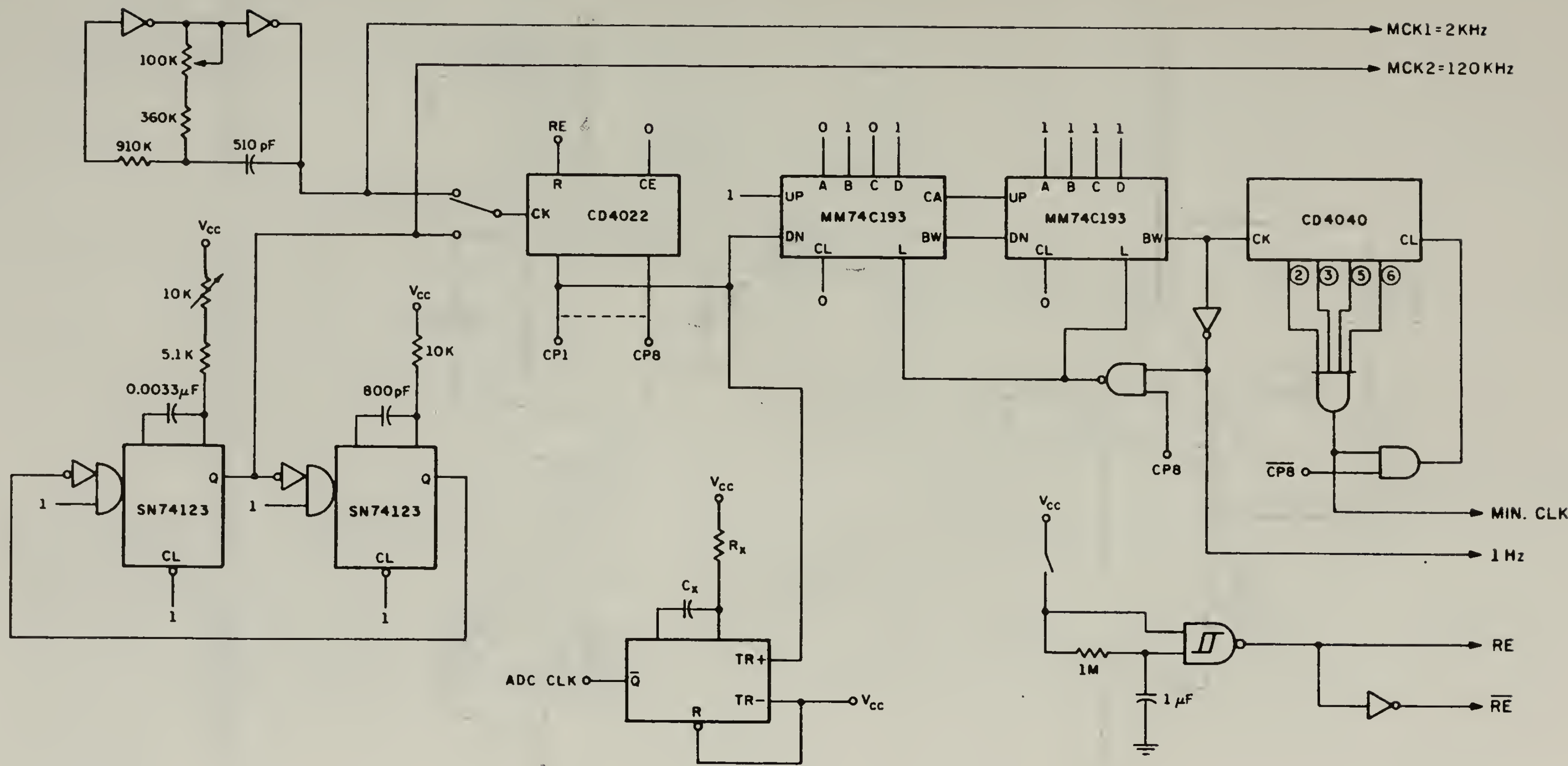


Figure A2. System Clock Circuit Diagram

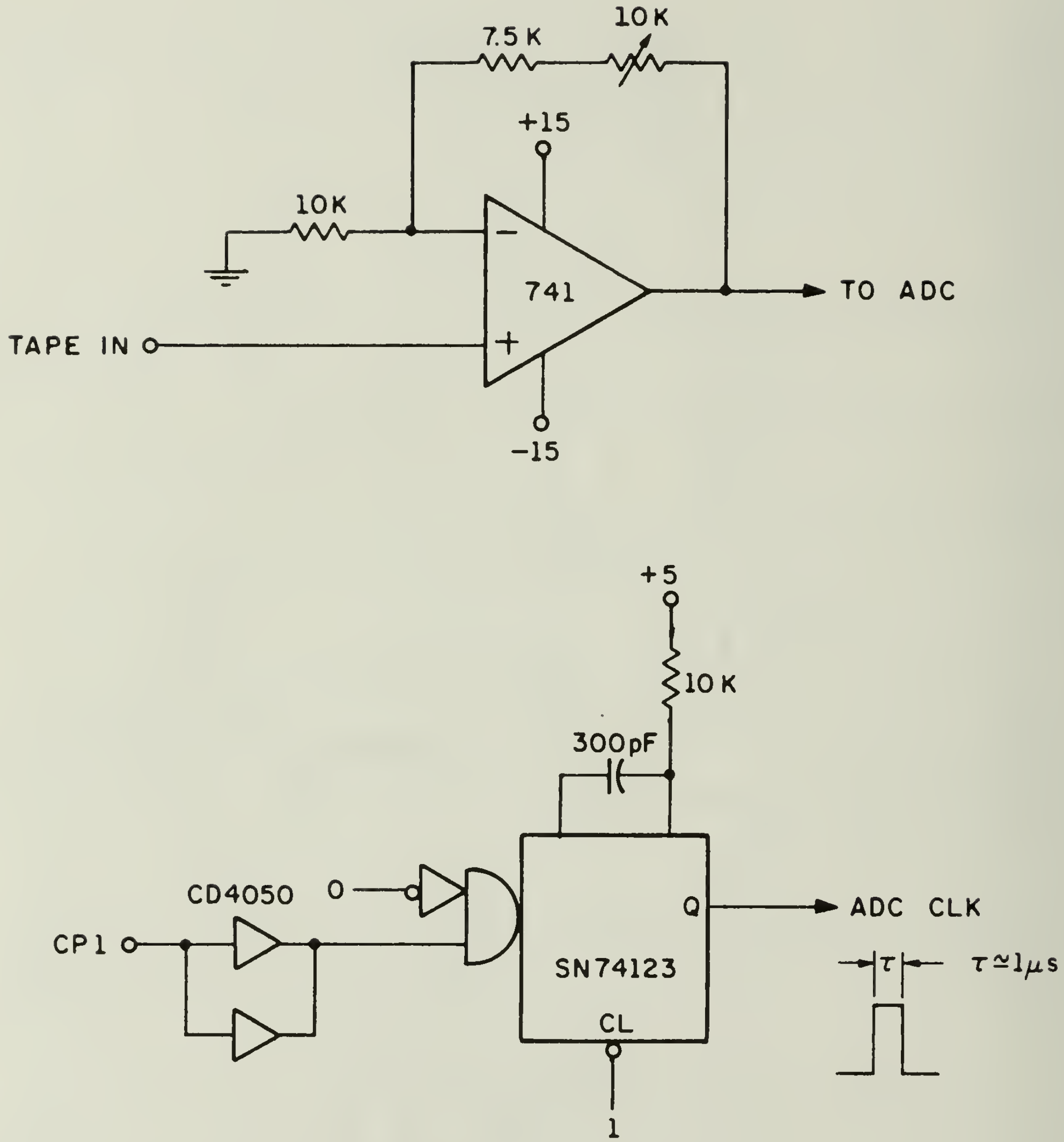


Figure A3. Tape-Analyzer Amplifier and ADC Clock for X60 Real-Time Operation

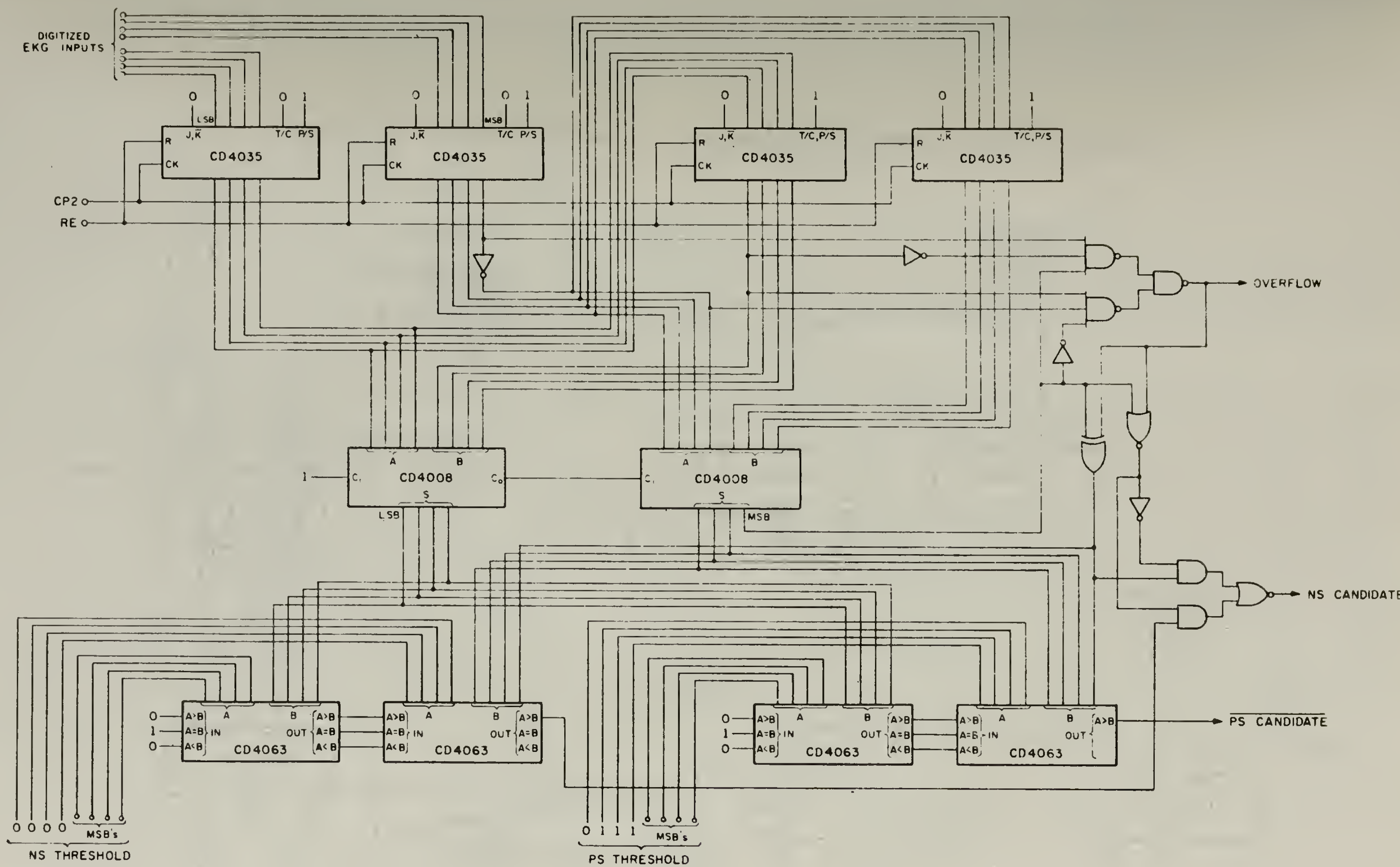


Figure A4. The Preprocessor Circuit Diagram

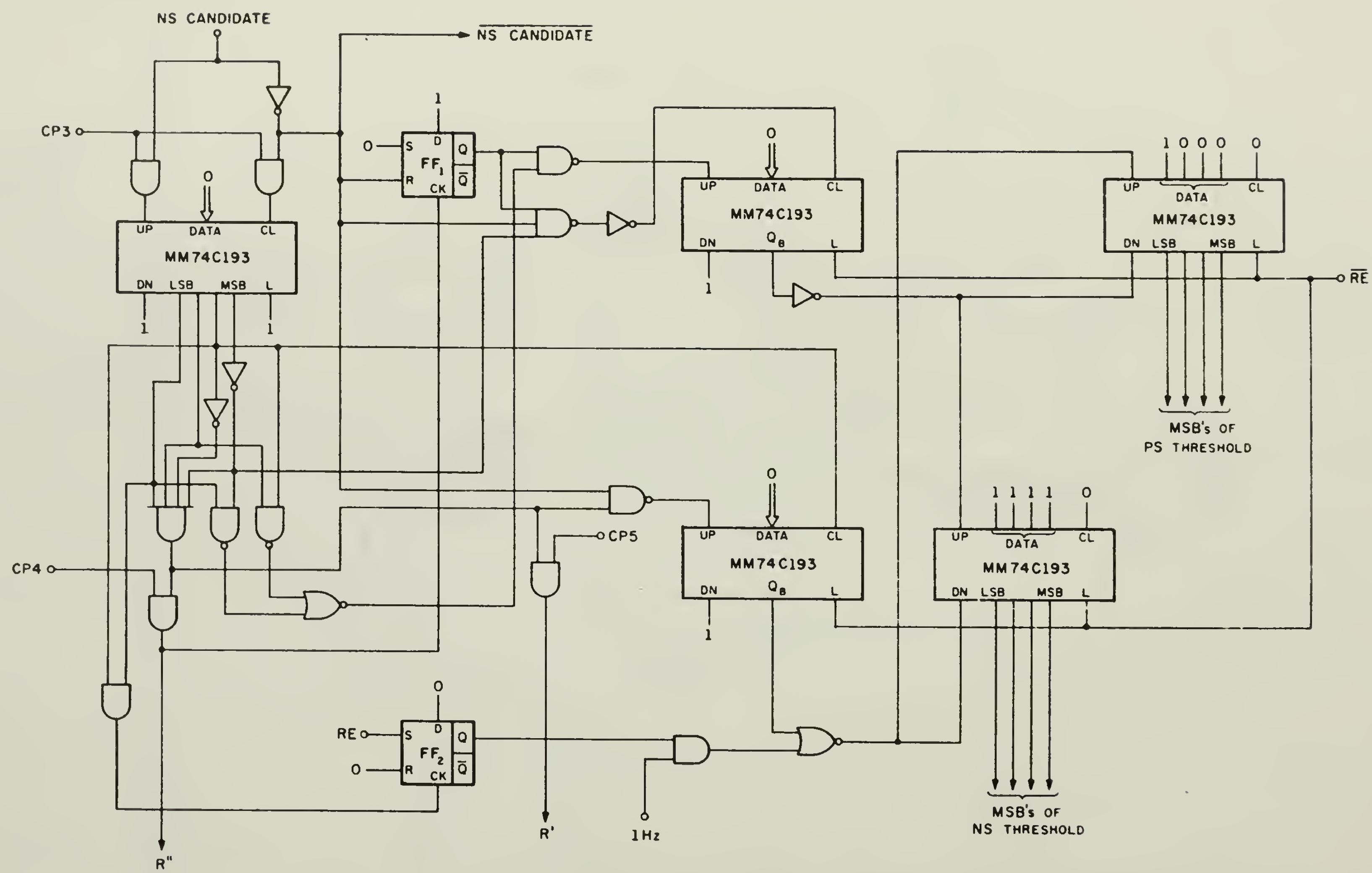


Figure A5. Circuit Diagram of the Adaptive Automatic Threshold Control

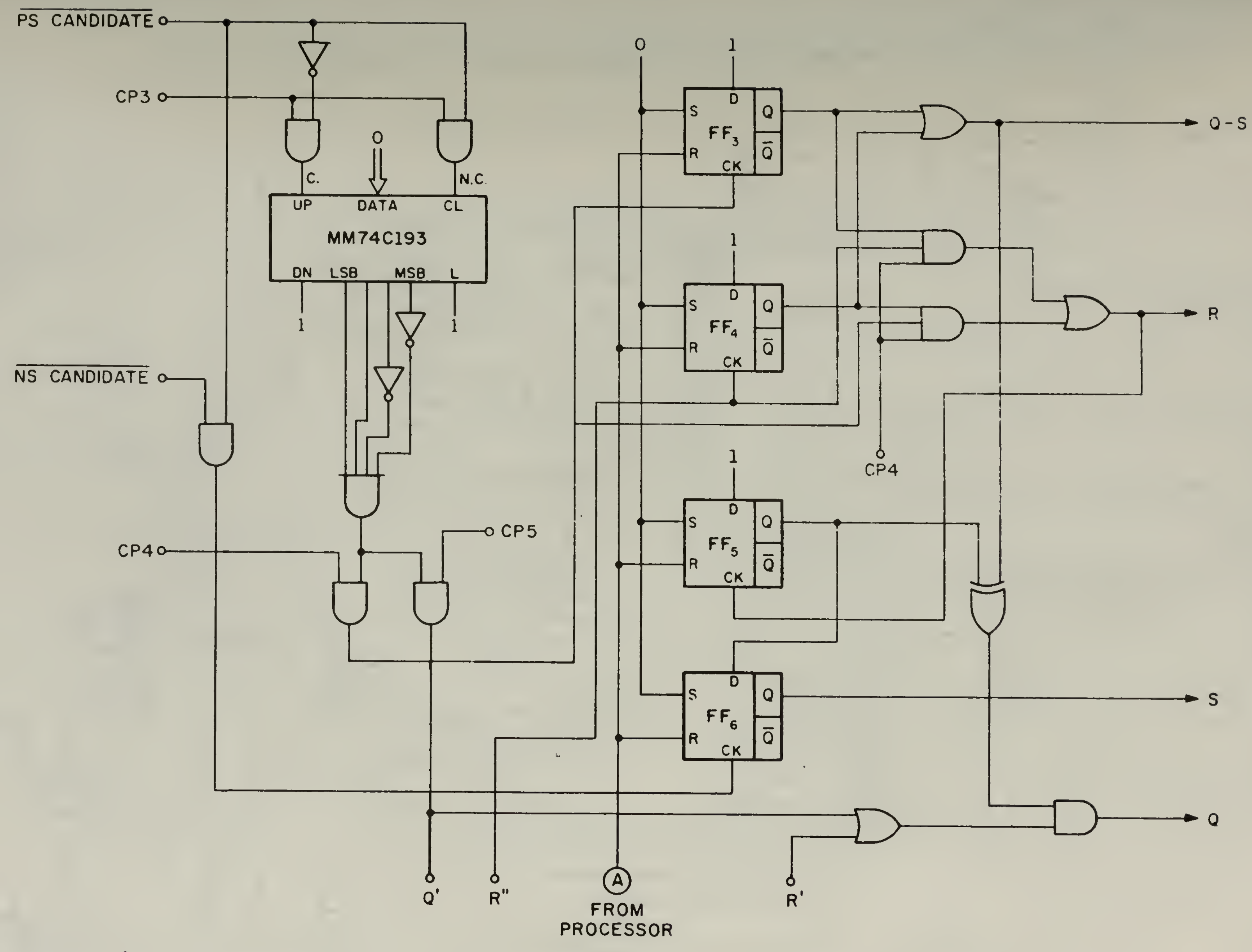


Figure A6. The Q, R, S Discrimination Logic Circuit Diagram

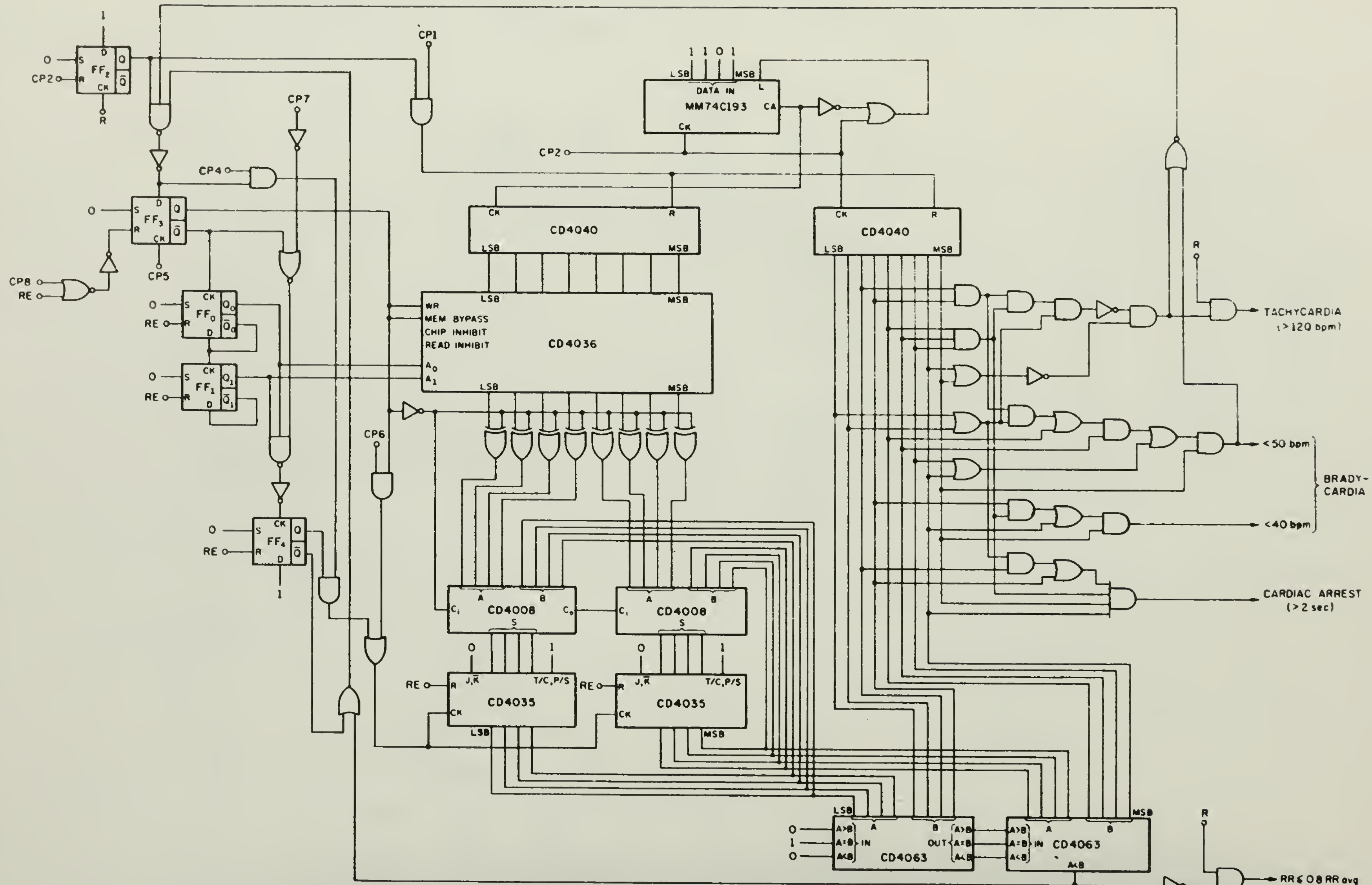


Figure A7. The RR Processor Circuit Diagram

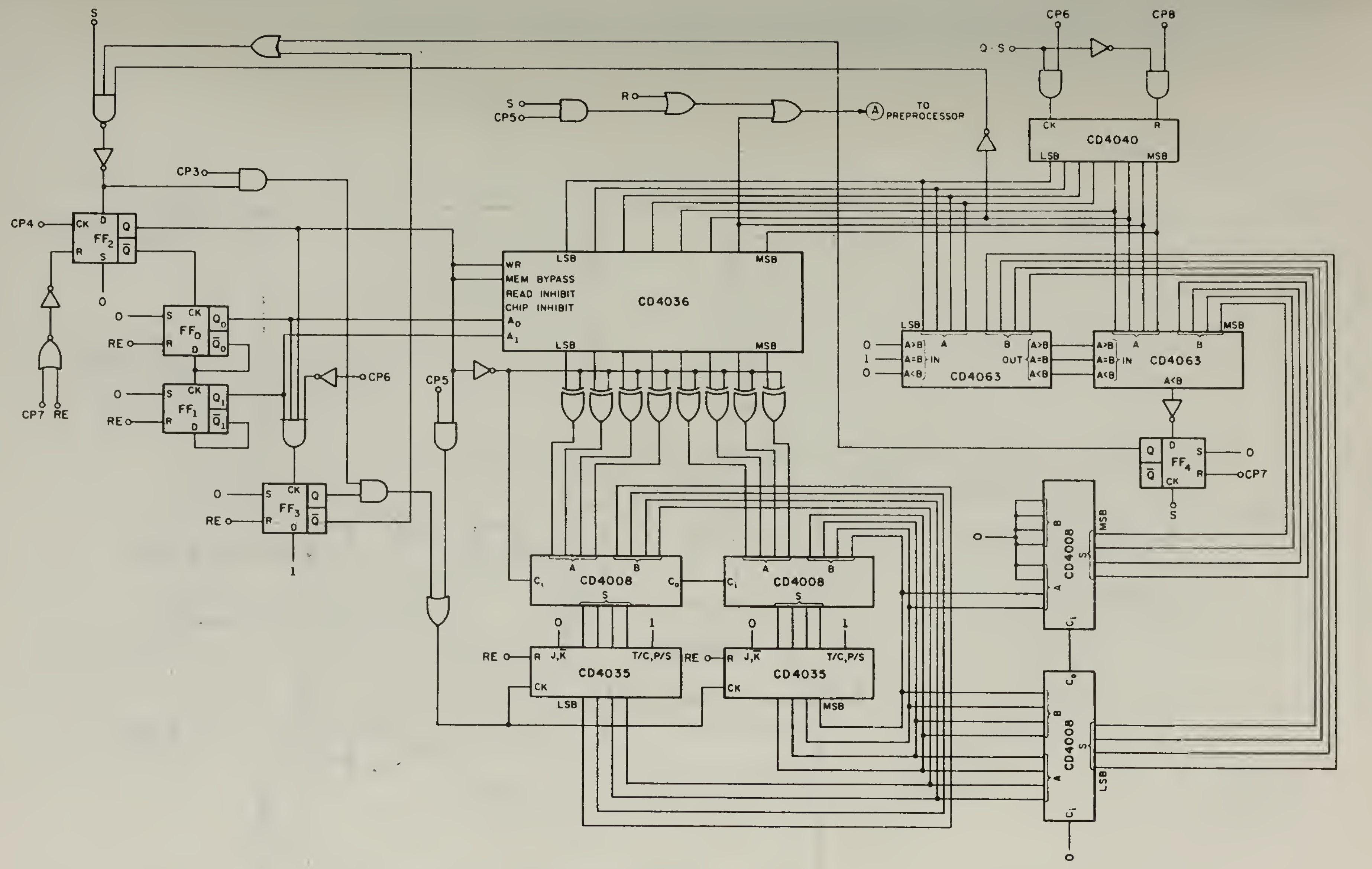


Figure A8. The QRS Processor Circuit Diagram - version 1

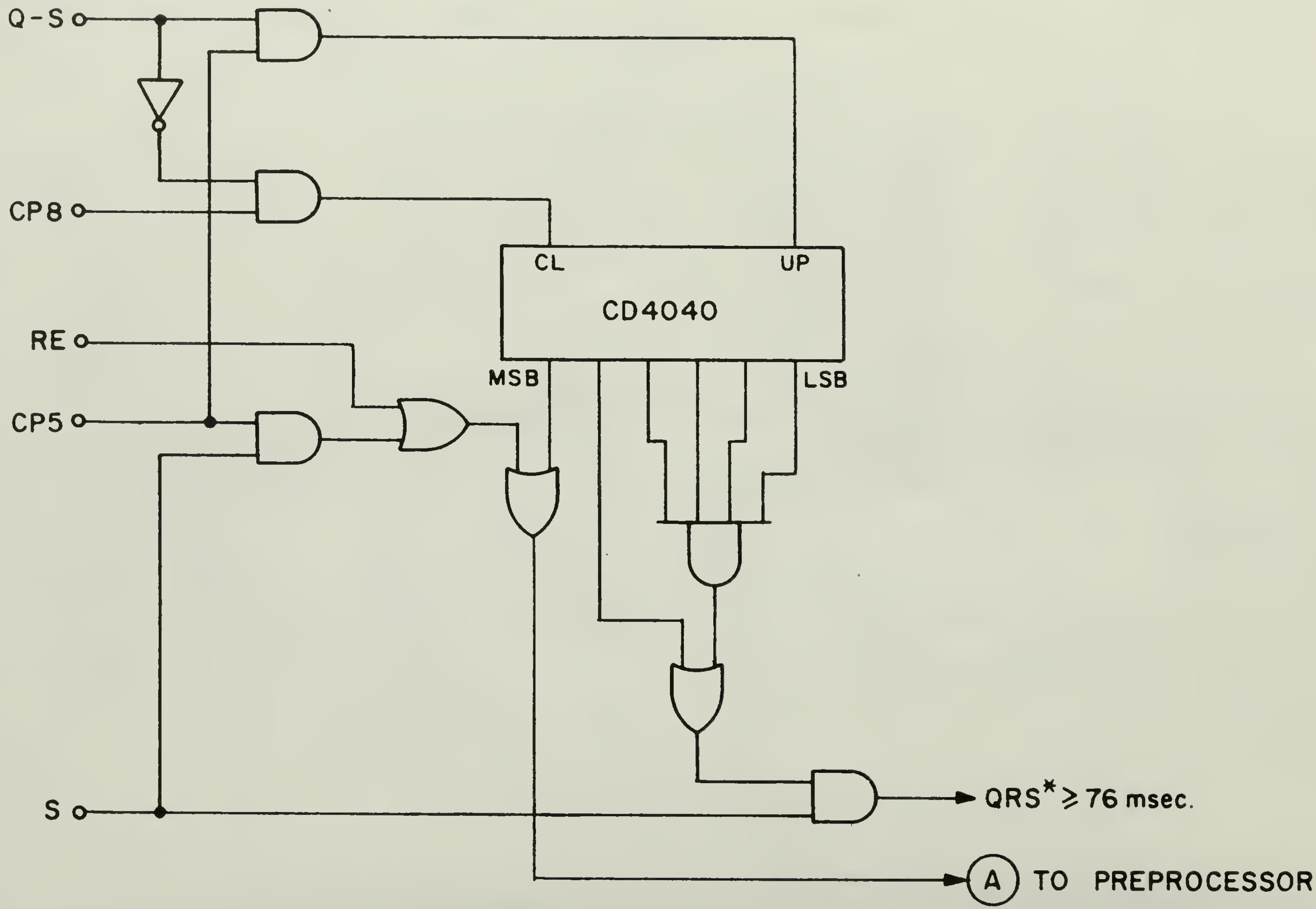


Figure A9. The QRS Processor Circuit Diagram - version 2

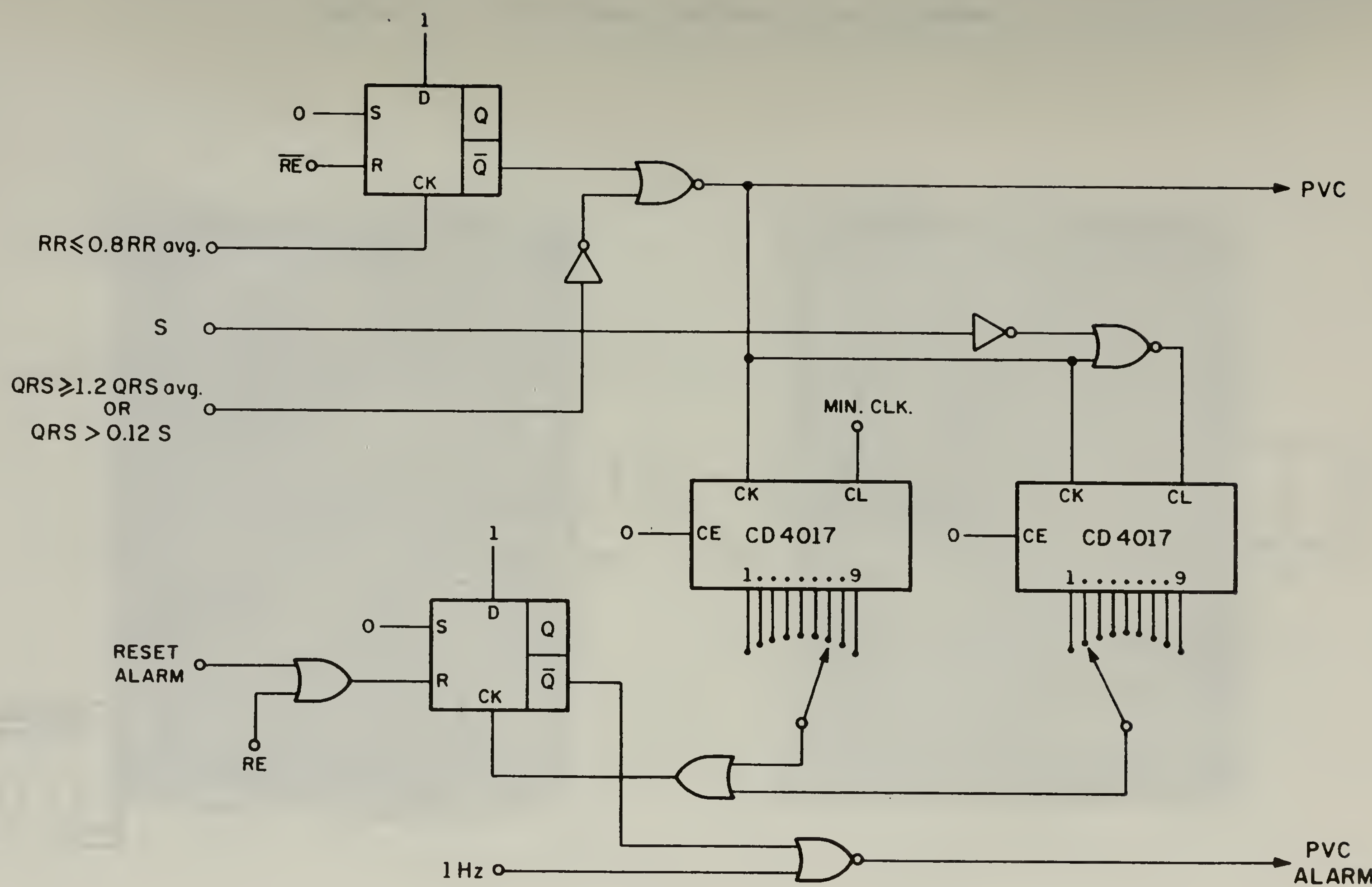


Figure A10. PVC Alarm Circuit Diagram

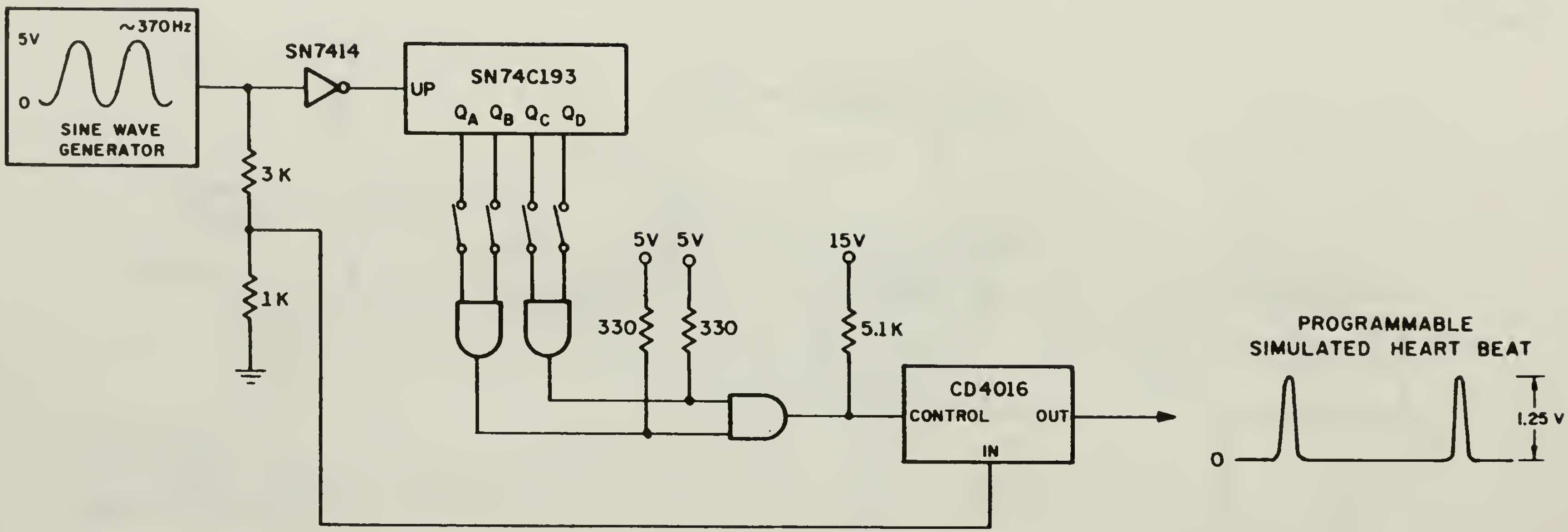
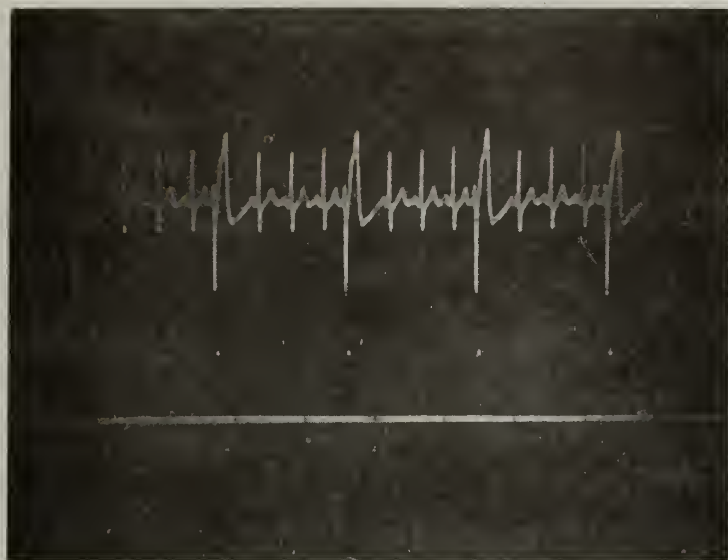


Figure A11. Heart Beat Simulator Circuit Diagram



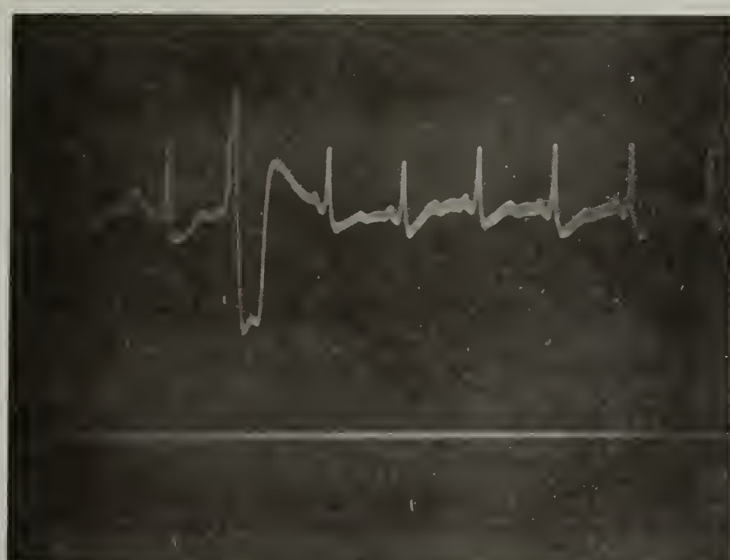


Figure A12. More Cases of PVC Detection

Figure A13. Picture of Cardalert

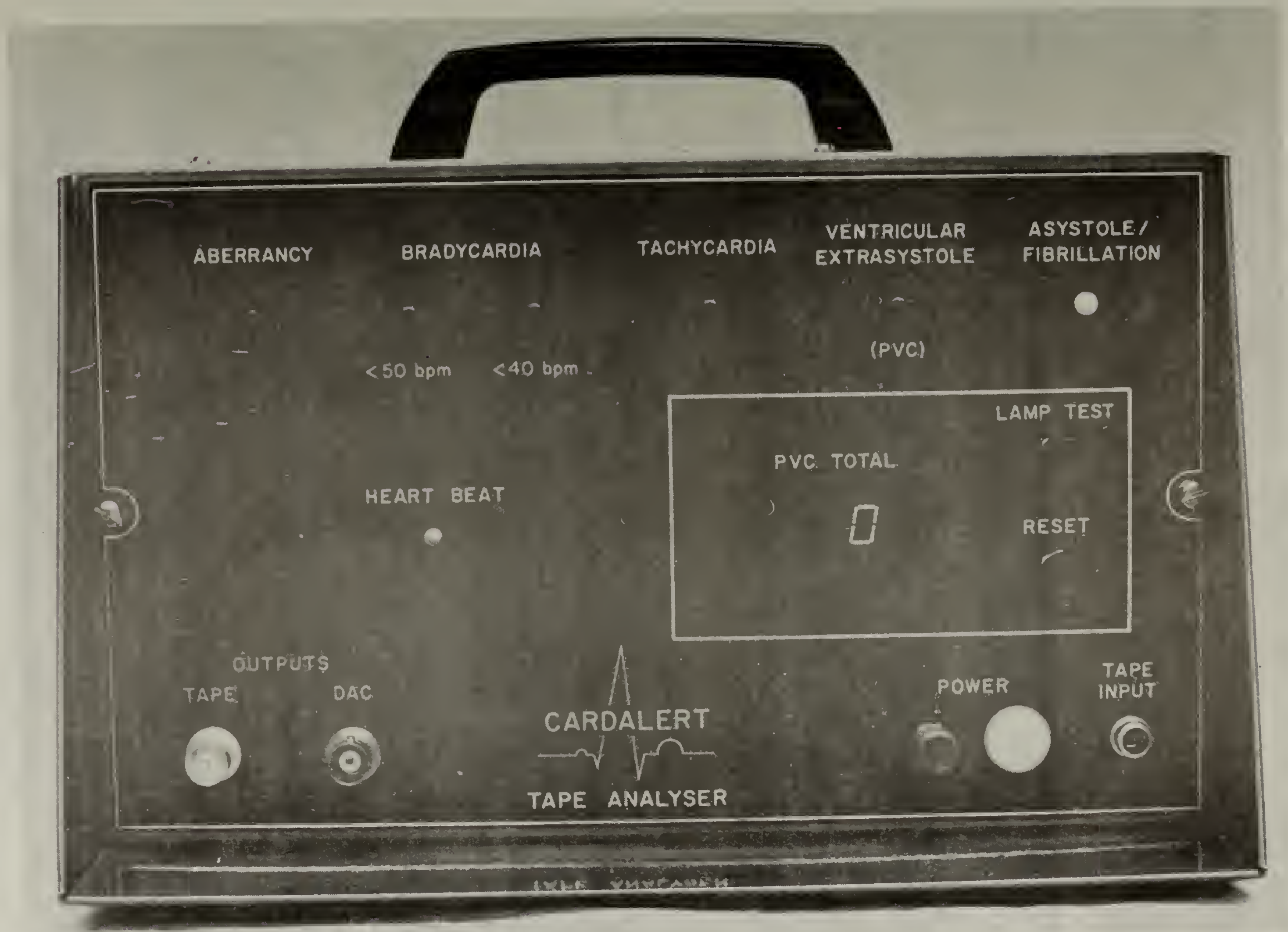


Figure A14. Front Panel of Cardalert Tape Analyser Unit

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VITA

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16. Abstracts

Cardalert is a portable, battery-operated real-time heart-beat processor and alarm system for high risk cardiac patients. Electrocardiograms taken from Lead II skin electrodes are converted into eight-bit digital data sequences. Digital differentiation is performed on the data and a feature-extraction approach is utilized to locate the Q, R, and S peaks. Comparison between the present RR-interval and a running average of the previous four normal RR-intervals is performed. Wide QRS durations are also noted. A conclusion is then derived from these parameters regarding the number and frequency of premature ventricular contraction (PVC) occurrences. An alarm is sent out when a presettable criterion is met to warn the patient of possible ventricular fibrillation. ECG tape analysis at 60 times real-time speed is possible by simply connecting the machine to an adaptor. Several arrhythmias are also recognized by the machine.

17. Key Words and Document Analysis. 17a. Descriptors

Cardalert, Arrhythmia, Premature Ventricular Contraction, Electrocardiograms, Preprocessor, ORS Processor, RR Processor

17b. Identifiers/Open-Ended Terms

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